UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

THE TRUSTEES OF THE WELFARE AND PENSION FUNDS OF LOCAL 464A – PENSION FUND, et al., Individually and on Behalf of All Others Similarly Situated, Plaintiffs, vs. MEDTRONIC PLC, et al., Defendants.	Civ. No. 0:22-cv-02197-KMM-SGE CLASS ACTION FIRST AMENDED CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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The Phoenix Insurance Company Ltd. and The Phoenix Provident Pension Fund Ltd. ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined in ¶¶27-31, *infra*), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of Defendants' public documents, conference calls, and announcements made by Defendants; U.S. Securities and Exchange Commission ("SEC") filings, and wire and press releases published by and regarding Medtronic plc ("Medtronic" or the "Company"); analysts' reports and advisories about the Company; statements by percipient witnesses; documents obtained from the Food and Drug Administration ("FDA") pursuant to the Freedom of Information Act; and other publicly available information. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. INTRODUCTION AND SUMMARY OF THE FRAUD

1. This case concerns two related frauds: (i) a scheme to cover up quality problems with Medtronic's flagship MiniMed insulin pumps; and (ii) misrepresentations about Medtronic's and its executives' dealings with the FDA, approval of the next-generation MiniMed pump, compliance with applicable regulations, and facility quality and inspections.

A. Background to the Fraud

2. Medtronic is a global healthcare technology company that was, during the Class Period, divided into four business segments, called "Groups." Relevant to this action is the Diabetes Group, which manufactures, monitors, and sells the MiniMed insulin pumps out of the group's Northridge, California headquarters (the "MiniMed Facility"). During the Class Period, the MiniMed pumps were the Diabetes Group's flagship products responsible for the lion's share of the group's revenues.

3. Leading into and during the Class Period, investors were intently focused on the Diabetes Group. Once hailed as Medtronic's "fastest growing" business segment, the Diabetes Group had grown its global insulin pump market share from 58% in 2009 to about 70% in 2017.[1] Key to this extraordinary growth was the MiniMed 600 Series pumps, and in particular the MiniMed 670G, which was revolutionary when it was released in 2017 and touted by one market observer as one of "Medtronic's most noteworthy clinical accomplishments."

4. Given the Diabetes Group's exponential growth, the market understood that revenues and profits stemming from the Diabetes Group were vital to Medtronic's success. But leading into the Class Period, Medtronic faced growing competition in the diabetes space, and the Diabetes Group's performance was stagnating. Analysts were concerned, and they repeatedly questioned Defendants on their plans to "turn this [Group] around." To assuage the market's concern, Defendants pledged that they were "laser-focused on doing what it takes to return to market growth" in the Diabetes Group, were "confident that we can

[1] Emphasis is added and citations are omitted throughout unless otherwise indicated.

turn it around," and that doing so was "a top priority for us" and a "key strategic focus." A central component of this "turnaround" was continuing to sell the MiniMed 600 Series pumps while seeking FDA approval of the Company's next-generation insulin pump – the MiniMed 780G – which Defendants billed as the product that would resuscitate the Diabetes Group.

5. Unfortunately for, and unknown to, Medtronic's customers and investors, the MiniMed 600 Series pumps and the MiniMed Facility responsible for manufacturing and monitoring those devices were plagued with dangerous quality issues. These concealed product problems threatened the Company's already flagging position in the diabetes market and imperiled FDA approval of the mission-critical, next generation MiniMed 780G, the application for which was based on the original application for the MiniMed 670G and submitted by the same plagued MiniMed Facility.

6. Unable to deliver their promised diabetes "turnaround" organically, Defendants resorted to fraud. First, they employed numerous artifices designed to deceive investors and regulators by covering up massive product problems related to the MiniMed 600 Series and older pumps, as well as severe and pervasive deficiencies at the MiniMed Facility responsible for the 600 Series and 780G pumps. Second, after a damning FDA inspection report detailing systemic deficiencies at the MiniMed Facility, Defendants made eight misleading statements designed to mislead the market about the status of ongoing discussions with the FDA, the approval status of the MiniMed 780G, the Company's regulatory compliance, and the dire state of its facility quality and compliance.

B. The Cover-Up Scheme

7. From the beginning of the Class Period through December 15, 2021, Medtronic and the Presidents of the Diabetes Group – Hooman Hakami and Sean Salmon (together with Medtronic, the "Scheme Defendants") – engaged in deceptive conduct for the purpose of covering up severe product quality issues with the MiniMed pumps and systemic risk management and regulatory deficiencies at the MiniMed Facility, thereby causing the price of Medtronic stock to trade at artificially inflated levels.

8. Known to the Scheme Defendants but concealed from customers and investors, all MiniMed 600 Series pump models, including the 670G, featured a defective "retainer ring," which was meant to lock together the pump and insulin cartridge. The faulty retainer ring prevented the insulin reservoir from properly sealing onto the pump, causing the over- or under-delivery of insulin resulting in serious, life-threatening conditions up to and including death. Between June 2016 and November 2019, Medtronic received a flood of more than ***74,000 complaints*** related to the defective retainer ring, yet refused to institute a recall or otherwise alert patients to the dangerous pumps. The Scheme Defendants justified their say-nothing approach by manipulating risk management procedures to estimate the probability of harm, which kept the estimate artificially low to avoid triggering a recall. During this same period, the Scheme Defendants were aware of dangerous cybersecurity defects in Medtronic's insulin pumps that left customers vulnerable to hacking and unauthorized injections of insulin, yet refused to inform their customers, initiate a recall, or even conduct an investigation into the vulnerability. As a further part of their scheme, the

Scheme Defendants orchestrated and publicized small, controlled studies that they used to advance the false narrative that Medtronic's insulin pumps were safe and effective.

9. But the Scheme Defendants could not hide these dangerous problems forever. In August 2019, Medtronic stealthily began releasing MiniMed 600 Series pumps with updated, supposedly more robust, black retainer rings, but left pumps with the older, less robust clear retainer rings on the market. Shockingly, they did not warn users of the potential dangers posed by their pumps. Then, given the mounting consumer complaints, in November 2019, Medtronic issued a "Field Safety Notification" directing users of only two models of 600 Series pumps to self-examine their pumps' retainer ring and notify the Company if the ring appeared damaged or missing. However, Medtronic insisted this action was "voluntary," "not a recall," and instructed its employees "to not replace defective pumps that were outside the warranty period." Despite these efforts to evade disclosing the danger posed to patients who used the MiniMed pumps, the FDA stepped in on February 12, 2020 and publicly determined the safety notice was, in fact, a Class I recall – the most serious type – causing the price of Medtronic stock to decline.

10. Hakami and Salmon knew of these severe product quality problems by virtue of their positions as Presidents of the Diabetes Group (Hakami from the beginning of the Class Period until he was terminated in October 2019 and Salmon from October 2019 through the end of the Class Period). Hakami and Salmon both routinely spoke to investors about their close management of the Diabetes Group, pointing to the MiniMed pumps as the group's most important product – one that they monitored extremely closely. Indeed, according to a confidential witness, Salmon was a hands-on manager who attended monthly

product review meetings and monitored all developments in the Diabetes Group. Moreover, Hakami's abrupt termination as the product problems reached a boiling point – one month before Medtronic's Field Safety Notification – and Hakami's and Salmon's outsized, suspicious insider sales as the cover-up continued further evidences their scienter.

11. But the retainer ring defect was only the tip of the iceberg. Hidden from the market were severe and pervasive risk management failures at the MiniMed Facility – failures that had helped to hide the retainer ring defect from the market for years. But it was only a matter of time before these regulatory deficiencies would come to light. That is because when the FDA learns of a Class I recall, federal regulations dictate that the FDA may initiate an inspection to determine the root cause(s) of the problem. Thus, at the earliest opportunity in light of the global pandemic that broke out a month after the February 2020 recall, the FDA conducted a month-long inspection of the MiniMed Facility from June 7, 2021 to July 7, 2021.

12. On July 7, 2021, the FDA reported its findings of myriad deficiencies and presented "Management Discussion topics" to senior management at a "closing meeting." That same day, the FDA issued a Form 483 to the Diabetes Group documenting severe, pervasive, and fundamental risk management and reporting deficiencies associated with the MiniMed Facility's monitoring, evaluation, and response to patient complaints about the MiniMed pumps. Specifically, the Form 483 determined that the Diabetes Group: (i) used an incorrect risk threshold when evaluating the danger posed by the 600 Series pumps; (ii) failed to adequately review and investigate complaints regarding failed retainer rings, both

the old and the supposedly fixed versions; and (iii) failed to timely notify the FDA of reportable pump malfunctions and resulting serious injuries.

13. The deficiencies identified in the Form 483 went to the MiniMed Facility's fundamental ability to monitor the safety of its products, notify customers of dangerous defects, and submit required reports of product failures and serious injuries to the FDA. The "objectionable conditions" identified in the Form 483 were far from minor or easily remedied. Indeed,

> Unlike a lab that simply required more detailed cleaning or missing equipment servicing records, based on my knowledge and decades of relevant experience, these deficiencies were not easily or quickly fixed. Rather, ***these deficiencies implicated an entrenched lack of adequate safety and compliance procedures that were necessary to ensure that device defects and complaints arising from devices coming out of the Northridge facility were adequately investigated, remediated, and reported to the FDA***.

Declaration of Philip T. Lavin, Ph.D., attached hereto as Exhibit A ("Lavin Decl."), ¶15. Accordingly, "these fundamental deficiencies, which implicated the Northridge facility as a whole, required protracted remediation efforts that could take ***a year or more*** to complete, document, and verify for effectiveness." *Id.*

14. Following receipt of the Form 483, Defendants scrambled to address the deficiencies. On July 28, 2021, Salmon sent his first of five letters to the FDA in which he acknowledged that the MiniMed Facility required "***broad, systemic***" remediation in order to address the Form 483 deficiencies. Over 68 pages, Salmon privately documented the extensive remediation efforts that the Diabetes Group planned to undertake over the coming months. In update letters sent in September, October, November, and December 2021, Salmon informed the FDA that remediation efforts continued, with estimated completion

dates spanning into 2022 and 2023. The necessary remediation actions that Salmon identified were "time consuming activities which, collectively, would take a year or more to complete, document, test for effectiveness, and present to the FDA, not including FDA feedback and time to sign off on completed tasks." Lavin Decl., ¶18.

C. The Misrepresentations

15. Following receipt of the Form 483, and as the scheme continued, Defendants issued eight misleading statements concerning their interactions with the FDA, approval of the 780G, regulatory compliance, and facility quality and investigations. These misrepresentations occurred between August 2021 and December 2021.

16. First, Salmon and Martha characterized their recent interactions with the FDA as "***really good***" and "***very positive***." Salmon similarly represented that "we're seeing really good interactive back and forth." The very next day, Salmon dumped almost half of his Medtronic holdings for proceeds of $3.8 million in trades executed ***outside of a Rule 10b5-1 trading plan***. This one-day sales binge was wildly out of line with Salmon's prior sales activity, having sold ***no*** shares in the three-year period preceding the Class Period. Later, Salmon assured investors that "we've had ***very good interactive conversations with the FDA***." In truth, Salmon's and Martha's recent interactions had been marred by a negative inspection, a damning Form 483, and unsuccessful letters to the FDA outlining the "broad, systemic actions" necessary to bring the MiniMed Facility back into compliance.

17. Second, Salmon represented that the 780G approval process was "***on track***" for approval by April 2022 and that Defendants were "***making good progress in the review***." Martha stated that Defendants were in "***active dialogue*** with [the FDA] on these approvals

with our pump." And when speaking about the timeline for 780G approval, Salmon stated that there was "***nothing different*** than what we've been talking about all along." In truth, given the inextricable link between the MiniMed Facility and the 780G approval process, the 780G could not be approved until the extensive remediation efforts were completed, documented, checked for effectiveness, and confirmed by the FDA. *See* Lavin Decl., ¶16. From the outset, these efforts would take a year or longer to complete, not including necessary time for the FDA to review and approve the remediation efforts. *Id.*, ¶15. Accordingly, at the time Defendants spoke, there was no possibility that the 780G would be approved on the market's expected timeline – an expectation that Defendants cultivated with their misrepresentations and omissions.

18. Third, Martha and Parkhill represented that Medtronic "***adhere[s] to regulatory requirements, such as those set by the U.S. FDA***." They also touted Medtronic's "facility quality and compliance." But at the time they made these statements, they were aware of the negative inspection and the Form 483's severe and pervasive deficiency findings. The inspection itself was notable, with the June-July 2021 inspection constituting the ***only*** inspection of the MiniMed Facility during the Class Period. And the Form 483 findings were even more alarming given their pervasiveness and the fact that ***95%*** of the Company's external regulatory inspections resulted in ***no*** findings.

19. Fourth, Defendants warned of the purportedly potential risk that FDA inspections "can" lead to the receipt of a Form 483, which "could" lead to the FDA "refus[ing] to grant pending pre-market approval applications." Although these risks were

couched as potentialities, they had already occurred – the MiniMed Facility had been inspected and Defendants had received a damning Form 483 that stalled 780G's approval.

D. The Truth Comes to Light

20. Due to Medtronic's widespread, unresolved deficiencies, the FDA formalized its Form 483 findings in a warning letter delivered to Medtronic on December 15, 2021 (the "Warning Letter"). The Warning Letter established that the MiniMed Facility utilized incorrect risk thresholds when evaluating the danger posed by the 600 Series pumps; failed to adequately review and investigate complaints; failed to adequately review and investigate new complaints regarding the supposedly fixed replacement retainer rings; failed to timely notify the FDA that Medtronic's pumps had caused "reportable serious injury"; and failed to timely notify the FDA of reports that its devices may be malfunctioning in a manner "likely to cause or contribute to a death or serious injury, if the malfunction were to recur."

21. Investors were blindsided, and the price of Medtronic's stock price fell precipitously. Later, Defendants finally admitted that the 780G would not contribute revenue to the Company in fiscal year 2023 due to the deficiencies identified in the Warning Letter, causing yet another steep stock price decline. As a result, investors suffered billions of dollars in monetary damages.

II. NATURE OF THE ACTION

22. This is a federal securities class action on behalf of all purchasers of Medtronic common stock between May 23, 2019 through May 26, 2022, inclusive (the "Class Period"), which seeks remedies under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the

"Exchange Act"), as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA") and Rule l0b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

III. JURISDICTION AND VENUE

23. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)), and SEC Rule 10b-5(a)-(c) promulgated thereunder (17 C.F.R. §240.10b-5). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act.

24. Venue is proper in this district pursuant to 28 U.S.C. §1391(b) and §27 of the Exchange Act. Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this district. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this district. In addition, the Company's principal executive offices are located in this district.

25. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and the facilities of a national securities exchange.

IV. THE PARTIES

26. Plaintiff The Phoenix Insurance Company Ltd. and The Phoenix Provident Pension Fund Ltd. purchased Medtronic common stock during the Class Period as set forth in the previously filed certification (ECF 27-2, 27-3) and incorporated herein, and was damaged thereby.

27. Defendant Medtronic plc is an Irish corporation with its principal place of business in Minneapolis, Minnesota. The Company's stock trades on the New York Stock Exchange under the ticker symbol "MDT."

28. Defendant Geoffrey S. Martha joined the Company in 2011. Martha served as Medtronic's President from November 2019 until April 2020. Before becoming its President, Martha was Executive Vice President ("EVP") of Medtronic's Restorative Therapies Group. Martha took over as Medtronic's CEO on April 27, 2020 and Chairman of the Board in December 2020.

29. Defendant Karen L. Parkhill is and was the Company's EVP and Chief Financial Officer ("CFO") throughout the Class Period.

30. Defendant Sean Salmon joined Medtronic in 2004. Salmon served as President of Medtronic's Diabetes Group from October 2019 until May 2022. Salmon is currently the President of the Cardiovascular Portfolio.

31. Defendant Hooman Hakami served as the President of the Diabetes Group from May 13, 2014 through October 21, 2019, when he was replaced by Salmon.

V. RELEVANT FACTUAL BACKGROUND

A. Advanced Insulin Pumps and Continuous Glucose Monitors

32. Before animal cells can burn glucose for energy, the glucose first needs to enter the cell. In humans and many other mammals, insulin is a hormone produced by the pancreas that causes cells to become porous to glucose, thereby regulating the amount absorbed by cells or present in the bloodstream. Diabetes is the disease of this system, and it can occur in two types. Type 1 diabetes develops when pancreatic cells are mistakenly

destroyed by the body's immune system, leaving the body with insufficient, or no, insulin. In Type 2 diabetes, the body produces sufficient insulin, but the body's cells have stopped responding to it, leaving them impermeable to glucose. More than 95% of people with diabetes have Type 2, which is far easier to treat, usually requiring only medication and lifestyle changes.

33. For the 5% of Type 1 diabetes patients globally – and an estimated 1.45 million in the United States alone – management of the disease is more complex, requiring precisely calibrated infusions of insulin. In non-diabetic healthy adults, blood glucose concentrations typically range between 80-120 milligrams per deciliter ("mg/dL"). Straying outside the range in either direction is dangerous. Hyperglycemia (blood glucose concentrations that are too high) can result in neuropathy, retinopathy, blindness, and other complications. Hypoglycemia (blood glucose concentrations that are too low) is dangerous within minutes and can be fatal within hours, as the glucose-starved heart and brain cells begin to die, causing fatal arrhythmias and seizures.

34. For decades, common practice was to inject insulin manually, via syringe, multiple times a day. The advent of the insulin pump, however, simplified diabetes management. Insulin pumps lock onto an accompanying insulin cartridge using a part called a "retainer ring." Rather than introducing several units of insulin into the body all at once via injection, insulin pumps allow a constant drip of miniscule, calibrated amounts of insulin over time, resulting in better control over blood glucose levels, and increasing the amount of time a diabetic can spend with their blood glucose level within the target range (sometimes referred to as "time in range"). The baseline drip of insulin is called the "basal rate." At

mealtimes, to control the resulting blood glucose spike, a one-time delivery of insulin is required. Such a delivery is called a "bolus."

35. Insulin pumps must be precise. If the insulin cartridge is not locked firmly into place, *e.g.*, due to a faulty or damaged retainer ring or software error, under- or over-delivery of insulin can occur. Delivering too much insulin can cause hypoglycemia, resulting in a near-immediate medical emergency. Until recently, insulin pumps had no way of knowing what the patient's blood glucose level was – they simply responded to the wearer's commands, delivering a set basal rate and boluses as directed. The most advanced pumps can integrate with continuous glucose monitors ("CGMs"), which are worn on the body and constantly monitor the wearer's blood glucose level. Combining a CGM with a pump results in what the industry calls a "hybrid closed loop system," which can adjust the basal rate of insulin in response to changes in the user's blood glucose level. They cannot, however, deliver automatic boluses at mealtimes. Pumps that can deliver such boluses are called "advanced hybrid closed loop systems," and might come close to achieving what the human pancreas does effortlessly – respond to changes in blood glucose levels in real time, even after meals, and deliver calibrated amounts of insulin with little to no intervention from the user.

B. Medtronic and Its Diabetes Group

36. Medtronic is an Irish company with its headquarters and principal place of business in Minneapolis, Minnesota. Medtronic describes itself as "the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions." Doing so is lucrative: for fiscal

year 2020 ("FY20"),[2] the Company reported nearly $30 billion in net sales, over $2 billion spent on research and development, 90 thousand employees worldwide, over 49 thousand patents, and over 72 million patients served.

37. At the start of the Class Period, Medtronic organized itself into four reportable business units, which it called "Groups": Cardiac and Vascular; Minimally Invasive Therapies; Restorative Therapies; and Diabetes. Three of the four groups contain subdivisions, as follows:

Group	Division
Cardiac and Vascular	Cardiac Rhythm & Heart Failure
	Coronary & Structural Heart
	Aortic, Peripheral & Venous
Minimally Invasive Therapies	Surgical Innovations
	Respiratory, Gastrointestinal & Renal
Restorative Therapies	Brain Therapies
	Pain Therapies
	Spine
	Specialty Therapies
Diabetes	*-no subdivisions-*

[2] Medtronic's fiscal year (or "FY") ends on the last Friday in April of each calendar year and begins immediately thereafter. Thus, the first quarter (or "Q1") of each fiscal year ends on the last Friday in July of the preceding calendar year, the second quarter (or "Q2") ends on the last Friday in October of the preceding calendar year, the third quarter (or "Q3") ends on the last Friday in January of the current calendar year, and the fourth quarter (or "Q4") and the FY itself end on the last Friday in April of the current calendar year. For example, Q1 2020 covered the period from April 27, 2019 to July 26, 2019; Q2 2020 covered July 27, 2019 to October 25, 2019; Q3 2020 covered October 26, 2019 to January 31, 2020; and Q4 2020 covered February 1, 2020 to April 24, 2020.

38. Historically, the Diabetes Group contributed billions of dollars in top-line revenue to the Company, generating between $2.1 billion and $2.4 billion in each FY18, FY19, and FY20. The Diabetes Group was also Medtronic's fastest growing segment in 2018, with one analyst highlighting "momentum in this [diabetes] franchise." A July 21, 2017 article entitled "Medtronic's Diabetes Segment Generating Excitement" similarly noted that the Diabetes Group was Medtronic's "fastest growing segment in the company's portfolio" and that "[i]nvestors are excited about its prospects due to the 670G insulin pump." Globally, Medtronic's Diabetes Group was a heavyweight. In 2009, Medtronic had 58% of global insulin pump market share; the next four biggest players were Roche Diagnostics (12%), Johnson & Johnson (11%), Insulet Corporation (10%), and Deltec (6%). By 2017, Medtronic was estimated to have 70% of the insulin pump market.

39. Coming into the Class Period, Medtronic's flagship insulin pumps were the MiniMed 600 Series, including models 620G, 630G, 640G, and 670G. Released in 2017, the 670G was the first pump from any manufacturer to integrate a CGM, thus becoming a "hybrid closed loop system." One publication touted the 670G under the headline "Artificial Pancreas," calling it one of "Medtronic's most noteworthy clinical accomplishments." With its ability to adjust the basal rate in response to changes in blood glucose levels, the 670G was expected to help the Diabetes Group stave off intensifying competition and maintain Medtronic's dominant status in the market. As relevant here, the MiniMed 600 Series models used the same overall pump body design and would eventually all be subject to the same recall.

40. The MiniMed 670G was of particular importance to Medtronic. Leading into and during the Class Period, Defendants repeatedly touted the MiniMed 670G as almost singlehandedly buoying the otherwise floundering Diabetes Group. Quarter after quarter during the Class Period, the Company stated that the Diabetes Group's financial performance was "primarily attributable" to or "driven by" "strong demand" for, or the "ongoing launch" of, the MiniMed 670G.

C. Unbeknownst to the Market, the MiniMed 600 Series Pumps Suffer From Severe Product Defects

41. For years leading into and during the Class Period, the MiniMed 600 Series pumps suffered from an undisclosed manufacturing defect related to the retainer ring used to seal the pump with the insulin cartridge. Beginning in June 2016 through November 2019, the Diabetes Group received more than ***74,000*** complaints regarding the defect, yet disclosed nothing to the market. Defendants were able to mask the defect by employing inappropriate risk analysis protocols that kept the estimated risk of harm artificially low, failing to adequately investigate and address the defect, and failing to report complaints of the defect to the FDA.

42. Also unknown to the market were dangerous cybersecurity defects that rendered Medtronic pumps susceptible to potential unauthorized access by individuals other than the user, resulting in potential "***catastrophic harm to patients***." As the FDA later concluded, Medtronic did not notify customers of the safety issue and failed to adequately investigate the potential data breaches.

43. Medtronic also orchestrated and publicized small, controlled studies meant to create the impression that the MiniMed 600 Series pumps were safe and effective. These studies were published in July 2018 and May 2019 – at the same time Medtronic was receiving thousands of complaints regarding the concealed retainer ring defect and was aware of the cybersecurity vulnerabilities.

44. In August 2019, Medtronic began stealthily releasing pumps with updated, supposedly more robust retainer rings. But they did not alert customers using pumps with the old retainer ring of the potential danger. Then, in November 2019, Medtronic issued a "Field Safety Notification" regarding the MiniMed 600 Series retainer ring defect, but insisted the action was "not a recall" and declined to replace defective pumps that were out of warranty. On February 7, 2020, the FDA determined that the notification constituted a Class I recall – the most serious type. Undeterred, Defendants downplayed the recall and concealed that the defects persisted for years as a result of the Diabetes Group's failure to manufacture, analyze, monitor, and report quality issues, in violation of applicable regulations.

D. Medtronic Announces the Next-Generation MiniMed 780G Pump and Shuffles Company Leadership

45. As the undisclosed device and facility defects persisted, the Diabetes Group's performance overall was stagnating. And although the MiniMed 670G was cutting edge when released in 2016, by the Class Period, it was lagging behind competitors' pumps with advanced hybrid closed-loop capabilities, most notably Tandem's flagship pump the "t:slim X2."

46. Medtronic's answer to Tandem's superior product was the MiniMed 780G. The 780G used the same overall pump body design as the 670G, meaning it uses the same vertical "modern" look of the 670G. However, the 780G possessed advanced hybrid closed-loop technology and would, according to the Company, be capable of over-the-air updates, iterative algorithm improvements, and Bluetooth connectivity. In the United States, managing "design controls for the entire Diabetes [Operating Unit]" – including the 670G and 780G – was the responsibility of the MiniMed Facility in Northridge, California.[3] The MiniMed Facility is also the U.S. manufacturer of the exported 780G.[4]

47. Almost immediately upon announcing the Company's "pivotal trial" of the 780G on June 8, 2019, Medtronic began pointing to it as the Company's next-generation insulin pump and touting its advantages over Tandem's product.

48. Analysts were hopeful that Medtronic could level the playing field against Tandem. On June 9, 2019, UBS wrote that Medtronic "thinks the 780G performance could top 670G and beat out competitors like t:slim X2." Per UBS, Medtronic expected the 780G to have "time in range of >80% vs. the mid 70% range for t:slim and to target glucose levels of 100 mg/dL in the night and day vs. times when TNDM [Tandem] levels can reach 120 and 160 mg/dL in those periods, respectively." Another supposed advantage was Medtronic's superior software, which would allow "780G's average time in auto mode [to] be ~99% vs.

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[3] The MiniMed Facility was also responsible for managing customer complaint handling, recalls, and medical device reporting.

[4] FDA Establishment Registration & Device Listing https://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfRL/rl.cfm?lid=744977&lpcd=OZP.

91% for TNDM and [to] have automated meal handling, potentially giving MDT ease of use and clinical advantages."

49. As pressure from competitors in the diabetes space and the impacts of the concealed product quality and facility problems continued to mount, Medtronic decided it was time to show Hakami, head of the Diabetes Group, the door, and in October 2019, Medtronic announced that he was leaving the Company. One market observer noted that during Hakami's five-year tenure as head of the Diabetes Group, Medtronic had ceded significant market share to competitors: "continuous glucose monitor devices like Dexcom's G6 and Abbott's FreeStyle Libre [have] grow[n] in popularity as insulin pump offerings like Tandem Diabetes's t:slim X2 and Insulet's Omnipod also posted big gains."

50. One month later, on November 19, 2019, the Company hosted its first earnings call since announcing that Martha would be taking over as CEO effective April 27, 2020. On the call, Martha acknowledged that "***[r]einvigorating our Diabetes business is also a priority***" and that Medtronic needed to "get back to leading the innovation in this space." The outgoing CEO also fielded questions from analysts about the MiniMed 780G, underscoring that ***"[t]he most important product launch we have is the 780G***."

E. The Diabetes Group Submits Its Application for FDA Approval of the 780G in February 2021, Which Was a "Supplement" to the Previously-Approved 670G Application

51. The 780G was submitted for FDA approval on February 22, 2021. The application for the 780G was a "PMA supplement" to the application used to obtain approval for the successor pump – the 670G.

52. The official applicant that submitted the 780G PMA was the MiniMed Facility. The medical device record that the Company submitted was a "PMA supplement" to "[t]he original PMA for the MiniMed 670G system." According to the FDA, a "PMA supplement" – rather than a new, standalone PMA – can be used to make certain changes or updates to an extant device.[5] *See also* Lavin Decl., ¶6. For example, a PMA supplement can be used when a company wishes to add an additional indication or institute a label change for an existing medical device.[6] *See also id.* As relevant here, the PMA supplement for the 780G indicated that the purpose of the supplemental application was to institute a "Labeling Change" to the "original PMA" for the 670G, which would allow the use of the 780G's updated Bluetooth and sensor technology on the insulin pump. *See* Lavin Decl., ¶7. The link between the 670G and 780G is made clear by the 780G's Summary of Safety and Effectiveness:

> The original PMA for the MiniMed 670G system (P160017) was approved on September 28, 2016, for use in persons ages 14 years and older.
>
> The current Panel Track Supplement was submitted to introduce the MiniMed 780G System, ***which updates the pump control algorithm*** from the Hybrid Closed Loop (HCL) algorithm to the Advanced Hybrid Closed Loop (AHCL)

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[5] *See* https://www.fda.gov/medical-devices/premarket-approval-pma/pma-supplements-and-amendments ("A PMA supplement is the submission required for a change affecting the safety or effectiveness of the device ***for which the applicant has an approved PMA***[.]"); *see also* https://www.advamed.org/wp-content/uploads/2021/05/advamed_accel-regulatory_guides-pma.pdf ("***Once a device has been approved by FDA***, companies are required to submit supplementary applications to make changes that affect product safety and effectiveness."). And the statutory definition of "PMA supplement" provides: "PMA supplement means a supplemental application to ***an approved PMA*** for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference therein." 21 C.F.R. §814.3.

[6] *Id.*

algorithm and to ***add compatibility to the new Guardian 4*** Continuous Glucose Monitor (CGM) as an alternative CGM component for the system.

F. Throughout 2021, Defendants Convey that the MiniMed 780G Would Receive Approval During Calendar Year 2021 or by April 2022 at the Latest

53. On February 23, 2021, Medtronic held its Q3 2021 Earnings Call. On that call, Martha told investors that the Diabetes Group was "gaining momentum with the successful launches of the 770G system in the U.S. and the 780G, which is now available in 26 countries across 4 continents" and that "we have now submitted the adult and the pediatric 780G insulin pump . . . to the FDA." Based on comments from Martha and others, analysts believed that the 780G would be approved during the 2021 calendar year. For example, on that same day, Guggenheim analysts noted a "likely launch for the 780G pump in the next few months."

54. On May 27, 2021, during Medtronic's Q4 2021 Earnings Call, Martha told investors that "the 780G and Guardian 4 sensor are under active review with the FDA." Following these comments, Wells Fargo analysts wrote that same day, "MDT's organic growth should accelerate over the coming quarters due to new product launches [including] the 780G diabetes pump. . . . Remain Overweight." The following day, on May 28, 2021, Jefferies analysts wrote: "With the launch of the 780G in the EU and ***FDA approval likely to follow in FY'22***" (*i.e.*, by April 2022 at the latest), "MDT will be better positioned not only to compete but to continue retaking share."

55. Based on Defendants' August 24, 2021 misrepresentations, the market continued to believe that the 780G would be approved by the end of 2021 or by April 2022 at

the latest. For example, an August 24, 2021 Barclays report stated, "780G and the G4 sensor are now being actively reviewed by the FDA, which, in our view, ***means approval could come before the end of this calendar year***." A Jefferies analysts stated that "the launch of the 780G/Guardian 4 in the EU and ***FDA approval likely in FY'22***." An August 24, 2021 J.P. Morgan analyst report stated, "780G pump remains under active review at the FDA with the ***hope of an approval in 2021***." An August 25, 2021 Deutsche Bank analyst report stated that "FDA approval of 780" was "***likely within the next couple quarters***." And an August 25, 2021 Morgan Stanley analyst report stated, "780G is currently under active FDA review, with approval timelines still hard to pinpoint; ***management does view approval prior to year-end 2021 as realistic***."

56. Similarly, based on Defendants' November 23, 2021 misrepresentations, the market continued to believe that Medtronic was having positive interactions with the FDA and that the 780G was on track for approval in FY22. For example, a November 23, 2021 UBS analyst report repeated Salmon's falsehood, parroting that Medtronic was "having ***good conversations with the FDA***" related to the 780G. A November 23, 2021 BTIG analyst wrote that FDA approval of the 780G was expected in 4Q21 of the calendar year (as opposed to Medtronic's fiscal year), and a November 27, 2021 Morningstar analyst report stated that "we anticipate FDA approval on the 780g pump" in "***spring 2022***."

G. On July 7, 2021, the FDA Inspects the MiniMed Facility and Issues a Damning Form 483

57. As discussed in §VII.E., *infra*, from June 7, 2021 through July 7, 2021, the FDA conducted an inspection of the MiniMed Facility. The inspection culminated in the

issuance of a Form 483, issued on July 7, 2021, which documented widespread, fundamental risk management and reporting failures associated with Medtronic's monitoring, evaluation, and response to patient complaints about the MiniMed pumps.

H. On December 15, 2021, Defendants Receive a Warning Letter from the FDA

58. As discussed §§VII.E.-F., *infra*, on December 15, 2021, Medtronic received the Warning Letter as a result of the Company's failure to address the deficiencies identified in the Form 483. The Warning Letter caused doubt among analysts as to whether the FDA would approve the MiniMed 780G in the next few years, let alone by the previously guided date of April 2022. On December 16, 2021, Wells Fargo analysts wrote that "Warning letters typically prevent approval of [Premarket Approval] devices" and noted that the Warning Letter "***could result in a delay to MDT's 780G pump . . . which is under review by the FDA and was expected to be approved in the US sometime in F[Y]2022*** (May 2021 – April 2022)." JP Morgan analysts noted on December 17, 2021 that "setbacks to the company's marquee pipeline assets, [including] the 780G . . . ***will likely take time to resolve***. . . ."

I. The 780G Is Delayed as Medtronic Attempts to Resolve the Severe and Pervasive Deficiencies at the MiniMed Facility

59. At a January 10, 2022 investor presentation, Martha acknowledged that the deficiencies at the MiniMed Facility required "***extensive remediation efforts***." Likewise, in February 2022, another executive in the Diabetes Group noted that the MiniMed Facility still has "***a lot of work to do***" to resolve the Form 483 deficiencies.

60. Ultimately, the deficiencies were not resolved and the 780G was not approved until April 2023.

VI. CONFIDENTIAL WITNESS ACCOUNTS

61. Former Medtronic employees have provided information demonstrating that Defendants' Class Period statements were false and misleading and that Defendants knew or recklessly disregarded the falsity or misleading nature of their statements. The CWs include individuals formerly employed at Medtronic during the Class Period, whose accounts corroborate one another, other sources set forth herein, and facts now admitted by Medtronic. The CWs provided information to Plaintiff's counsel and/or their investigator on a confidential basis and are particularly described by job description, responsibility, and duration of employment, thereby providing sufficient detail to establish their reliability and personal knowledge. As set forth below, the information provided by the CWs supports an inference that Defendants' Class Period statements were false and misleading and that Defendants acted with scienter.

62. Confidential Witness No. 1 ("CW-1") worked as a Diabetes Management Consultant and then Senior Territory Manager from June 2006 through April 2018 and a Principal Territory Manager between April 2018 and January 2022. CW-1 was responsible for the sale of the MiniMed 630G, 670G, and 770G pumps, including addressing product problems and coordinating with physicians and patients regarding issues that arose with the pumps. CW-1 was responsible for selling Medtronic's diabetes products and growing market share. CW-1 explained that during the Class Period, Medtronic faced intense competitive pressure from DexCom Inc., Tandem Diabetes Care, and Insulet Corporation

due to those companies' advanced and synergistic insulin delivery technologies. In particular, the integration of DexCom's continuous glucose monitor with Tandem's and Insulet's insulin pumps made them very strong competitors in the market. CW-1 explained that during the Class Period, there were at least four product problems with the MiniMed 670G system – a retainer ring issue, a blood glucose loop issue, a reservoir clogging issue, and an alarm sounding issue. Complaints relating to these issues were reported to a 24-hour helpline. CW-1 explained that these issues resulted in physicians and patients moving to competitor products. CW-1 stated that the MiniMed problems began when Hakami started to institute huge cost cuts to make the bottom line appear more profitable. CW-1 stated that Hakami "took an axe to the diabetes' operational budget." CW-1 stated, "we weren't selling more units, he [Hakami] was cutting the budget." CW-1 concluded that the MiniMed setbacks began under Hakami's leadership. CW-1 stated that they understood that executive management tracked revenues on a daily basis. This was done using the MM Sales database and, later in 2021, a Salesforce database. CW-1 stated that they departed Medtronic, in part, because they grew tired of having to constantly apologize to physicians and patients for issues with the MiniMed products.

63. Confidential Witness No. 2 ("CW-2") worked as a Senior Director, U.S. Regulatory Affairs, between October 2020 and August 2022. CW-2 managed a team of regulatory employees whose primary responsibilities included obtaining FDA approval for Medtronic devices, including the MiniMed 780G system. CW-2 was primarily responsible for all regulatory submissions related to the MiniMed 780G application after starting employment at Medtronic, and worked exclusively in the Diabetes Group. CW-2 stated that

executive management knew before receiving the Warning Letter that the MiniMed 780G would not receive timely approval but stated that "executive management continued to communicate misinformation to the public."[7] CW-2 stated that it would take approximately one to two years to remediate the deficiencies identified in the FDA's Form 483. CW-2 remarked, "it was physically impossible to get approval for any product while under a warning letter." CW-2 explained that the recall of the MiniMed 600 Series would have a negative impact and cause major delays for all associated and/or similar products that were in the premarket approval phase. CW-2 went on to explain that they had monthly meetings on the first Friday of each month with the FDA to discuss the progress of the MiniMed 780G application. CW-2 met with the FDA's product managers and branch chiefs to discuss the progress and timelines for the MiniMed 780G system. CW-2 explained that CW-2 coordinated with Dianaty, Ellul, Tilara, and Ito Wu (FDA Branch Chief) on these monthly meetings. CW-2 also explained that CW-2 attended monthly internal meetings, commonly referred to as "product review meetings," where the status of the MiniMed 780G application was discussed. These product review meetings were attended by approximately 150 individuals, including Salmon and Parkhill. CW-2 explained that executive management closely monitored the progress of FDA approval for the MiniMed 780G product, remarking that "this was our live or die product." CW-2 stated that "executive management did not clearly share MiniMed 780G's progress information with the public." CW-2 explained that

[7] CW-2 included Martha, Parkhill, Salmon, Que Dellara (replaced Salmon as head of Diabetes in May 2022), Austin Domenici (CFO of Diabetes), Chiraq Tilara (Vice President of Quality Management), Ali Dianaty (Vice President of Product Innovation), and Stacey Ellul (Vice President of Global Regulatory Affairs) in "executive management."

executive management knew that they were disseminating unrealistic timelines and dates to shareholders. CW-2 stated that they communicated on a weekly basis during and after team meetings with their boss – Ellul, who reported to Salmon, Dianaty, and Dellara throughout the Class Period – who also attended every FDA meeting. CW-2 stated that executive management was very hands-on and that "all developments in the Diabetes units were reported up the chain of command to the CEO." CW-2 stated that they informed executive management that MiniMed 780G had no chance of obtaining timely approval, but CW-2 was informed that "this information would not be disseminated to the public before the next analyst call, which was two weeks away." CW-2 explained that in November 2021, problems with FDA approval of the MiniMed 780G system became clear when a different FDA submission was stalled – CW-2 stated that "the FDA gave us a hint that a warning letter was coming." CW-2 departed Medtronic, in part, because they did not have faith in executive management and felt executive management propagated misinformation to the public and was unethical.

VII. RULE 10b-5(a) AND (c) SCHEME CLAIM

64. This section of the complaint alleges Rule 10b-5(a) and (c) scheme liability claims against the Scheme Defendants (as previously defined, the Scheme Defendants include Medtronic, Hakami (President of the Diabetes Group from May 2014 until October 2019), and Salmon (President of the Diabetes Group from October 2019 until May 2022)).

65. As alleged herein, between May 23, 2019 and December 15, 2021, the Scheme Defendants engaged in a scheme involving violations of federal regulations, artifices, manipulation of data, and concealment in order to deceive investors and cover up significant

ongoing quality problems with the Diabetes Group's portfolio of insulin pumps and the MiniMed Facility responsible for manufacturing, marketing, and monitoring them.

66. Throughout the Class Period, the Scheme Defendants concealed and understated pervasive and dangerous malfunctions occurring in the MiniMed 600 Series, MiniMed 508, and Paradigm insulin pumps, and knowingly failed to remove dangerous products from the market. They furthered their scheme of keeping investors and customers in the dark by implementing inappropriate risk analysis procedures to underestimate the risk of harm to users, failing to investigate device complaints, and failing to report patient incidents to the FDA, all in violation of applicable regulations. They also orchestrated several controlled, small-scale studies that touted the benefits of a limited number of functioning MiniMed 600 Series insulin pumps to users. When the truth concerning the financial and reputational ramifications concealed by the scheme was exposed through a series of partial disclosures including a Class I recall of the MiniMed 600 Series and the Warning Letter, investors suffered substantial monetary damages.

A. The Scheme Defendants Know Their Insulin Pumps Have a Dangerous Defect and Employ Improper Risk Analysis Procedures to Hide It

67. Leading into and during the Class Period, the Scheme Defendants conveyed that the 670G was singlehandedly buoying the Diabetes Group and touted the 780G's forthcoming approval. Behind the scenes, they had secretly been confronted – for years – by a flood of complaints regarding the MiniMed 600 Series pumps. Known to the Scheme Defendants but concealed from the public, Medtronic's 600 Series pumps were plagued with a potentially life-threatening manufacturing defect with their clear retainer ring.

Malfunctioning retainer rings could cause the insulin reservoir not to seat properly. With an improperly seated reservoir, the pump could unexpectedly deliver more or less insulin than commanded by the user, resulting in life-threatening hyper- or hypoglycemia.

68. Hakami, then-President of the Diabetes Group, was aware of this problem no later than June 2016, when the Diabetes Group initiated an internal study to address complaints regarding failing retainer rings on the 600 Series pumps. The FDA, when writing about this internal study in December 2021, said that Medtronic understated the risk posed by this defect and failed to warn customers of the potential for hazardous failure of the pumps.

69. The Diabetes Group's risk analysis calculations, conducted upon discovering pervasive and dangerous malfunctions with respect to the retainer rings in the MiniMed 600 Series pumps, inappropriately and consistently underestimated the likelihood that those pumps would harm patients. Nevertheless, the Scheme Defendants made the decision not to notify customers about the pervasive and dangerous malfunctions for ***three years*** based on the inappropriate risk analyses.

70. Beginning in June 2016, the Diabetes Group received thousands of complaints from customers regarding the MiniMed 600 Series retainer rings. In total, it received "***over 74,000 retainer ring complaints***, with over 57,000 of those reported to the FDA" as Medical Device Reports ("MDRs"), by November 2019 – coinciding with Hakami's termination. In November 2019, as Salmon took over as President, the Diabetes Group received at least one report that a patient was hospitalized with a defective 600 Series pump, and ***one report of a***

death "which [the Company] investigated and [was] unable to exclude as being associated with this issue."

71. Nonetheless, the Diabetes Group did not notify MiniMed 600 Series users of the true scope of the problems with its insulin pumps until it was forced to institute a full recall of the 600 Series in October 2021, as discussed below. *See* §VII.D., *infra*. The Diabetes Group justified the decision to stay silent based on the results of a flawed risk analysis protocol implemented to determine the risk associated with the complaints Medtronic was receiving about the malfunctioning retainer rings. The result of the faulty risk analysis protocol was the erroneous determination that "the risk of serious adverse health consequences was 'improbable.'"

72. The Diabetes Group used the results of this protocol, beginning in June 2016 and continuing through November 20, 2019 (under Hakami's leadership), to justify their decision to keep customers and investors in the dark about the very real and serious danger posed by the MiniMed 600 Series pumps. Indeed, the Diabetes Group initially considered informing customers of the ongoing malfunction of its pumps, but changed course and instead decided it would not do so.

73. According to the FDA, the Diabetes Group's "outcomes of risk assessment ***[did] not appear to be appropriate***." The FDA found that the Diabetes Group's initial risk assessment used a "risk calculation formula [which] underestimated the probability of occurrence of harm" and that "[c]onsequently, [Medtronic] did not initiate a correction or removal to address the defective devices."

74. As time went on and the number of complaints mounted, the Diabetes Group (under Salmon's leadership) repeated its assessment in November 2019, March 2020, and August 2020. To continue justifying its silence, all of these assessments used the same flawed calculation, which resulted in an artificially low probability of harm – even after a significant increase in complaints.

75. Eventually, with complaints mounting, the Diabetes Group had to manipulate the risk assessment protocol it had initiated in June 2016 to avoid elevating the calculated probability of harm. Specifically, it revised the formula in March 2021 in two important respects, the combination of which allowed Medtronic to repeat its flawed risk assessment and conclude the risk of serious adverse health consequences was "improbable," despite receiving tens of thousands of customer complaints. First, the Diabetes Group used the "Total Shipment of Affected Product" as its total population of MiniMed 600 Series devices. However, this metric was improper because it included devices that were not in use by patients, such as those that had been shipped to distributors but had not yet been distributed to customers, thereby artificially increasing the number of units in use. Second, the Diabetes Group increased the parameters on the risk evaluation matrix. This had the practical effect of requiring a higher occurrence for a harm to be classified as more serious (and thereby trigger the duty to initiate a recall).

76. By making these changes, the Diabetes Group was able to manufacture an estimated probability of harm that was low enough to justify its refusal to recall MiniMed 600 Series pumps that used the clear, less robust retainer rings. Despite an ever-growing number of customer complaints, the alterations to the risk analysis protocol resulted in yet

another internal determination, in June 2021, that harm was unlikely, which the Diabetes Group again used to justify not warning users of the potential danger. The result of this, according to the Warning Letter, was that Medtronic "failed to adequately remove the pumps containing the older, less robust ring from the market."

B. The Scheme Defendants Are Aware of Dangerous Cybersecurity Defects in Medtronic's Insulin Pumps, Yet Refuse to Fully Inform Customers, Initiate a Full Recall, or Conduct Proper Investigations

77. In 2018, the Diabetes Group initiated an internal study into a "cybersecurity vulnerability with the remote controllers used with [its] Medtronic MiniMed 508 Insulin Infusion Pump and [its] MiniMed Paradigm Insulin Infusion Pumps." This vulnerability allowed "unauthorized individuals" to access the software of the products in question in ways that could, according to Medtronic's internal investigation, "***result in catastrophic harm to patients***." However, upon making this determination, the Diabetes Group elected to leave these vulnerable devices on the market without informing its customers of the "safety issue."

78. The FDA found that this determination violated federal regulations, because although the Diabetes Group destroyed its current inventory of the vulnerable remotes and recalled just over 15,000 of the units that had been shipped in the four years prior to 2018, the Diabetes Group had been selling remotes susceptible to the cybersecurity breach in question for nearly 20 years – since 1999 – meaning that there were numerous dangerous products still in use. Crucially, according to the Warning Letter, Medtronic "did not notify all customers of this safety issue."

79. These failures to take dangerous products out of circulation and notify customers of the relevant safety issue violated 21 CFR §820.100(a).

80. The Scheme Defendants' failure to adequately investigate a potential data breach violated 21 CFR §820.198(c). On December 25, 2019, a user of a Paradigm insulin pump sent a complaint to Medtronic, recounting an instance in which the customer received over-injections of "insulin that were not programmed by the customer." However, even though the device in question was returned to Medtronic for analysis, the Diabetes Group's "investigation did not include reviewing the actual pump history to verify" the cause of the unauthorized injection. Instead, the Diabetes Group's cybersecurity Incident Response Management Team, which was tasked with investigating this complaint, closed the investigation in June 2021 after concluding that the cause of the event could not be determined. By doing so, the Scheme Defendants perpetuated the appearance that their diabetes products were safe and effective by keeping crucial information about potential cybersecurity vulnerabilities from customers and looking the other way when confronted with customer complaints.

C. The Scheme Defendants Orchestrate and Publicize Small, Controlled Studies Touting the Safety and Efficacy of the MiniMed 600 Series Pumps

81. While the Scheme Defendants were manipulating the results of the Diabetes Group's risk analysis protocol and concealing the MiniMed 600 Series' defects and customer complaints, they simultaneously orchestrated and publicized small, controlled studies that they used to advance the false narrative that MiniMed 600 Series pumps were safe.

82. In July 2018, after receiving tens of thousands of complaints, the Diabetes Group issued a press release regarding a study it conducted over the course of one year with 6,000 patients in cooperation with the insurance company UnitedHealthcare. In the press release announcing the study results, Hakami stated: "These positive results provide further evidence of the benefits of both automated insulin delivery and of value-based healthcare models." Hakami went on to tout Medtronic's commitment "to prioritize innovation that improves health outcomes and lowers healthcare costs." A study press release also cited clinical results compiled by Pratik Agrawal, a data scientist employed by the Diabetes Group, and touted the ability of the MiniMed 630G to "demonstrate 27 percent fewer preventable hospital admissions" compared to diabetes patients who manually inject insulin. (As discussed below, just over a year after Medtronic released the results of this study, Medtronic issued a safety notification regarding the MiniMed 630G and the FDA later classified that notice as a Class I recall. *See* §VII.D., *infra*).

83. The Diabetes Group continued the charade when, on May 9, 2019, it publicized the results of yet another study: the Study of MiniMed 640G Insulin Pump with SmartGuard™ in Prevention of Low Glucose Events in adults with Type 1 Diabetes, or the "SMILE" study. This study followed just 153 adults as they used the MiniMed 640G and purported to find that using the MiniMed pumps helped increase health outcomes for diabetics. The press release announcing the results stated that "the SMILE study demonstrated the effectiveness of the [MiniMed 640G] system in reducing hypoglycemia." (As discussed below, the FDA recalled the MiniMed 640G nine months later. *See* §VII.D., *infra*).

84. With these studies, the Scheme Defendants obfuscated the actual state of safety and reliability among the larger population of MiniMed 600 Series pumps. As they kept quiet regarding the growing number of dangerous malfunctions, the orchestration and publication of these studies presented a misleading picture to customers, the FDA, and investors regarding the safety and efficacy of the MiniMed 600 Series pumps.

D. The Scheme Defendants Issue Incomplete and Misleading Warnings Regarding the MiniMed 600 Series Retainer Rings, Leaving Dangerous Products in Circulation Until the Full Recall in October 2021

85. Eventually, the Scheme Defendants had to address the defects and dangerous malfunctions in the MiniMed 600 Series products. But they did so as quietly as possible and stopped short of issuing a recall, leaving dangerous products on the market for years.

86. In August 2019, Medtronic began stealthily releasing MiniMed 600 Series pumps with updated, supposedly more robust black retainer rings. However, Medtronic still did not advise users that all previously sold MiniMed pumps containing the older, less robust, clear retainer rings, or that any insulin pumps sold prior to that time using the software susceptible to cybersecurity breaches, could result in harmful and potentially fatal over- or under-injections of insulin.

87. Approximately four months after introducing the updated MiniMed 600 Series pumps with the black retainer rings, and more than three years after first becoming aware that the clear rings were dangerously malfunctioning, Medtronic finally informed customers that their insulin pumps were dangerous. On November 21, 2019, Medtronic issued a Field Safety Notification – a "voluntary" action and not, the Company insisted, a recall – directing

users of the 600 Series pumps to examine the pumps' retainer rings and notify the Company if the ring appeared damaged or missing. Medtronic included photos of reservoirs with a normal ring, a damaged ring, and a missing ring so that users could conduct their own inspection:

Image: Location of the retainer ring on the MiniMed™ 600 series insulin pump

88. Despite the fact that the MiniMed 600 Series pumps utilized the same overall pump body design, the November 2019 Field Safety Notification included only two models: the 630G and 670G.

89. The Field Safety Notification also included a phone number and website to contact Medtronic for further guidance. However, as the FDA later reported in the Form 483, Medtronic had instructed its employees to tell customers that the "***field action was not a recall***." Medtronic employees were "***also instructed to not replace defective pumps that were outside the warranty period***."

90. Despite the informal warning, on February 7, 2020, the FDA determined that Medtronic's November 2019 Field Safety Notification was, in fact, a Class I recall – the most serious type. According to the FDA, this designation signals there is "a reasonable probability that the use of or exposure to a violative product ***will cause serious adverse health consequences or death***." In addition to the 630G and 670G, the FDA included the

620G and 640G in its recall notices on February 7, 2020, citing the same problems with "broken or missing retainer ring[s] that prevent[] a proper lock" that could result in incorrect and potentially harmful doses of insulin. The recall was made public on February 12, 2020, causing Medtronic's stock to decline and investors to suffer monetary damages.[8] Analysts commented on the disappointing news and attributed Medtronic's stock price decline to the announcement of the Class I recall.

91. Nevertheless, the Scheme Defendants downplayed the scope of the problems and misleadingly conveyed that the retainer ring defect was the only problem at issue with the Diabetes Group's products, thereby deceiving the market as to the widespread deficiencies with its processes used to monitor, analyze, and report on those products to ensure patient safety. Analysts took them at their word, highlighting that the recall was limited and would not meaningfully affect the Company going forward. For example, as detailed in a February 12, 2020 Evercore ISI analyst report issued in response to the recall, Medtronic indicated it "believes the occurrence of 'retainer ring breaking' is less than 0.1%" and it "told its customer[s] that it will replace a small number of pumps that have the damaged rings – cost impact expected to be minimal."

92. Medtronic issued another letter to its customers on March 5, 2020 informing them of an "urgent recall" but downplaying the severity of the designation, writing that "a 'recall' as defined by the FDA 'does not always mean that you stop using the product or

[8] On February 7, 2020, the FDA issued recall notices for each of the 620G, 630G, 640G, and 670G insulin pumps. The FDA's February 12, 2020 summary included the 630G and 670G, the two models that were distributed in the United States.

return it to the company.'" As long as the retainer ring functioned properly, Medtronic wrote, it was safe to continue using the pump.

93. Notably, all of the steps that Medtronic took up to this point in time fell short of fully recalling all MiniMed 600 Series pumps from circulation, even though complaints and reports of injuries to MiniMed 600 Series users continued to flow in about the new, supposedly more robust black retainer rings. Indeed, according to the FDA, "[f]rom December 2019 to May 2021, [Medtronic] received 887 complaints of defective black retainer rings."

94. But, unknown to customers and investors, the retainer ring problems identified in the February 2020 recall were just the tip of the iceberg. Eventually, the full magnitude of the issues plaguing the MiniMed pumps and the processes employed at the MiniMed Facility to monitor, analyze, and report the Diabetes Group's products would come to light following the FDA's June-July 2021 inspection of the MiniMed Facility, and Medtronic's recall would expand in October 2021 to encompass any 600 Series insulin pump with a clear retainer ring – even those that did not have visible damage.

E. The FDA Investigates the MiniMed Facility

95. When the FDA learns of a Class I recall, federal regulations dictate that the FDA may initiate an inspection to determine the root cause(s) of the problem. *See also* Lavin Decl., ¶9 ("Following a Class I recall related to a device, the FDA routinely conducts inspections of the facility or facilities responsible for manufacturing and monitoring the device to determine the cause(s) of the defect, assess whether the defect has been remedied . . ."). In the case of the February 2020 recall of MiniMed 600 pumps, however,

that inspection was necessarily delayed by the global pandemic that broke out the month after the Class I designation. Accordingly, the FDA conducted an inspection at Medtronic's MiniMed Facility from June 7, 2021 to July 7, 2021.

96. On July 7, 2021, at the conclusion of its inspection, the FDA reported its findings of myriad deficiencies and presented "Management Discussion topics" at a "closing meeting" with Diabetes Group senior management (at this time, Salmon was the President of the Diabetes Group). The same day, the FDA reported its findings from the inspection in a Form 483, which was delivered to Medtronic's Vice President of Quality, Chirag Tilara. Over eleven pages, the FDA laid out in exacting detail the multiple, systemic deficiencies it found in each of three categories of "observations" that went well beyond the already significant manufacturing defects plaguing the MiniMed retainer rings:

> (1) Medtronic failed to establish adequate "procedures for corrective and preventive action" – referring to Medtronic's inappropriate risk analysis procedures;
>
> (2) Medtronic failed to investigate "[c]omplaints involving the possible failure of a device to meet any of its specifications"; and
>
> (3) Medtronic failed to implement "[w]ritten MDR [Medical Device Report] procedures."

The FDA also set out the corrective action that would be necessary to return the facility to compliance. In short, the inspection found that Medtronic had widespread, systemic process-based deficiencies and violations that resulted in concealing product problems and exposing users of Medtronic's product to dangerous products. *See also* Lavin Decl., ¶¶11-14 (summarizing the deficiencies identified in the July 7, 2021 Form 483). The FDA also

determined that the Diabetes Group consistently failed to investigate complaints or make required reports to the FDA. *Id.*

97. Then, on October 5, 2021, Medtronic issued a full recall of any MiniMed 600 Series insulin pump with a clear retainer ring, which it would replace "with one that has the updated black retainer ring at no charge."

98. Due to Medtronic's widespread, unresolved deficiencies, on December 9, 2021, the FDA formalized its negative findings from the MiniMed Facility inspection in a Warning Letter. The Warning Letter found that Medtronic utilized an incorrect risk threshold when evaluating the danger posed by the 600 Series pumps; failed to adequately review and investigate complaints regarding failed retainer rings; failed to adequately review and investigate new complaints regarding the supposedly fixed replacement retainer rings; failed to timely notify the FDA of a "reportable serious injury" potentially caused by one of Medtronic's defective pumps; and failed to timely notify the FDA of reports that its devices may be malfunctioning in a manner "'likely to cause or contribute to death or serious injury if the malfunction was to recur.'" *See also* Lavin Decl., ¶14. Upon the disclosure of the Warning Letter, the price of Medtronic stock declined precipitously.

F. The Warning Letter Details Medtronic's Repeated Failures to Abide by FDA Regulations

99. The misconduct described above repeatedly violated federal regulations that required Medtronic to: (i) establish appropriate procedures for corrective and preventative action, as required by 21 C.F.R. §820.100(a); (ii) review, evaluate, and investigate complaints involving possible device failures, as required by 21 C.F.R. § 820.198(c); and

(iii) submit reports to the FDA, known as Medical Device Reports or MDRs, documenting instances where a marketed device may have caused or contributed to a death or serious injury, as required by 21 C.F.R. §803.50(a)(1).

100. With respect to the Diabetes Group's failure to implement required procedures for corrective and preventative action, the Warning Letter determined that "there was a reasonable probability that the use of, or exposure to, the pumps manufactured with the clear retainer ring would cause serious adverse health consequences, including severe hypoglycemia which can result in loss of consciousness, seizure; severe hyperglycemia which can result in diabetic ketoacidosis or hyperosmolar hyperglycemic state, metabolic abnormalities; or death and classified the recall . . . as class 1." Nevertheless, the Warning Letter found, the Diabetes Group "failed to adequately implement procedures for corrective and preventive action (CAPA) in that you failed to adequately analyze all sources of quality data, failed to identify actions needed to correct nonconforming product, and you did not appropriately verify or validate the change to your device to ensure corrective and preventive actions taken were effective and did not adversely affect the finished device."

101. With respect to the Diabetes Group's failure to review, evaluate, and investigate complaints of device failures, the Warning Letter found that the Diabetes Group "failed to investigate over 800 complaints of defective black retainer rings." The Warning Letter described multiple instances where the Diabetes Group received complaints of defective pumps and adverse health results, failed to report those complaints, as required by applicable regulations.

102. With respect to the final category of regulatory violations, the Warning Letter detailed multiple instances where the Diabetes Group failed to submit required MDRs. For example, the Warning Letter explained that Medtronic did not submit any report to the FDA, at any time, upon learning of at least one instance in which a MiniMed 600 Series device may have "caused or contributed to [a death or] serious injury." The Warning Letter provides one "example" of an instance in which the "MiniMed Insulin Pump malfunctioned . . . [such that] treatment received by the patient was necessitated to preclude permanent impairment of a body function or permanent damage to a body structure." The Diabetes Group, according to the Warning Letter, never submitted a report of this incident, let alone within the required 30 days. The Warning Letter also provides numerous examples of instances where the Diabetes Group submitted MDRs beyond the required due dates.

103. The misconduct described above was perpetrated as part of the Scheme Defendants' scheme and course of business designed to mask the true state of affairs in the Diabetes Group. The scheme had the effect of misleading investors about the dire state of the Diabetes Group and the MiniMed Facility, the ballooning product quality and safety issues, and the impact the defects and facility-level deficiencies had on the approval of the MiniMed 780G pump. By concealing the true state of the Diabetes Group, the scheme maintained artificial inflation in the price of Medtronic stock, and investors suffered damages when the truth, was revealed through a series of partial disclosures.

G. The Scheme Defendants Acted with Scienter

1. Hakami and Salmon Were Hands-on Presidents of the Diabetes Group Who Closely Monitored the Business, Its Products, and Its Interactions with the FDA

104. Leading into and during the Class Period, the Diabetes Group had persistently under-delivered, with the Scheme Defendants and market analysts alike recognizing its shaky performance. As a result, the Scheme Defendants were intently focused on the Diabetes Group's performance, and specifically the performance of its insulin pump technology, as they themselves publicly asserted.

105. Market analysts' attention on the Diabetes Group meant that the Scheme Defendants likewise kept close focus on its developments and setbacks. As the Class Period began, market analysts questioned the Scheme Defendants about whether the Diabetes Group should even remain within Medtronic (as opposed to being divested by the Company):

- Morgan Stanley, May 23, 2019: "[D]o you think an independent Diabetes business would allow you to adapt or grow more quickly?"
- Goldman Sachs, June 11, 2019: "Do you think strategically it makes sense for you to hang on to this business in the medium term or might it be better served by not being part of Medtronic?"
- Morgan Stanley, September 10, 2019: "I was going to talk about – one of the business that struggled is Diabetes. You and I talked about this. We said – 1.5 years ago, we made the case of could this business be in a better position if it was outside of Medtronic. You spin Diabetes, you reinvest. . . . Why is this asset still best positioned inside Medtronic?"
- Barclays, March 11, 2020: "[T]he one area that continues to be a little bit of a drag is Diabetes. I just wanted to touch on that. How confident are you . . . that Medtronic can turn this around?"

106. To respond to analysts' queries concerning the viability of the Diabetes Group, the Scheme Defendants assured investors that they had closely monitored the Diabetes

Group's performance. During the Q4 2019 conference call on May 23, 2019, for instance, Hakami responded that the Diabetes Group "get[s] a lot of benefits from being part of Medtronic," particularly being able to leverage Medtronic's "scale and breadth" to "help[] us drive the growth that we need." Hakami confirmed his intimate knowledge of the Diabetes Group, providing analysts with "a few data points with respect to how we finished," to assure investors of the group's "competitive positioning." Hakami also confirmed he felt "really good about [the Diabetes Group's] ability to be accretive to overall Medtronic in FY '20," including because of the MiniMed products. Salmon similarly expressed his confidence in the Diabetes Group's prospects on February 18, 2020, despite recognizing that "the Diabetes business certainly has no small challenges to overcome," stating: "I can tell you I'm really very encouraged with how we're seeing some derisking of the pipeline that we have going forward."

107. The Scheme Defendants personally and repeatedly spoke about the Diabetes Group generally and the MiniMed 600 Series and/or 780G pumps specifically during the Class Period. For instance, during Medtronic's Investor and Analyst Briefing from ADA on June 9, 2019, Hakami discussed the Diabetes Group's "innovation pipeline," proclaiming that "[w]e're even more excited about the future for this business. And the reason we're even more excited about the future for this business is because we have never had a richer pipeline of innovation in the Diabetes Group, never." Hakami explained that the "670, for us, was never intended to be the end. It's actually intended to be the beginning," claiming that the Diabetes Group's upcoming "advanced hybrid closed-loop system" would be a "game changer" "just 12 months from now." Salmon echoed these sentiments, confirming

on February 18, 2020 that "[t]he 780G is an important catalyst for us to drive growth." Salmon further underscored on November 24, 2020 the importance of the 780G's launch in the United States, stating, "[o]bviously, the 780G launch in the U.S. is a big deal."

108. The Scheme Defendants' focus was expected given the mandate from Medtronic's CEOs that the Diabetes Group was a focal point for the Company. In particular, on the Q2 2020 earnings call on November 19, 2019, shortly after Martha became Medtronic's President, he identified the Diabetes Group's turnaround as one of his top three priorities, along with maintaining Medtronic's mission statement and growing market share throughout the Medtronic portfolio. Specifically, Martha affirmed on the call that "***[r]einvigorating our Diabetes business is also a priority***."

109. Salmon continued to reiterate that he closely managed the Diabetes Group. For example, in a December 14, 2020 Medtronic press release, Salmon was quoted: "Completing the turnaround in Diabetes remains a ***high priority for me***."

110. In short, as Presidents of the Diabetes Group, Hakami and Salmon were intently focused on, and publicly expressed their personal knowledge of, the Diabetes Group, its products, and its pipeline, especially its flagship insulin pumps. Indeed, in connection with the 2023 re-inspection of the MiniMed Facility, the Diabetes Group's new President – Que Dallara – acknowledged, as outlined in the accompanying Establishment Inspection Report, that as President she was "the most responsible individual at Medtronic MiniMed." With respect to product quality and compliance, Ms. Dallara indicated that she was "ultimately responsible for implementing corrective actions to address deficiencies" at the MiniMed Facility, including "through individuals under her chain of command." In turn, the

Diabetes Group's Vice President of Quality for the Diabetes Group indicated that his responsibilities included "general oversight of the Northridge quality management system and handling post-market actions (*e.g.*, field actions)" and that he "report[ed] directly" to the President of the Diabetes Group. Thus, the inference is strong that Hakami and Salmon, who also served as Presidents of the Diabetes Group during the Class Period, had similar responsibilities, including oversight of quality problems and corrective actions concerning the MiniMed 600 Series. Moreover, CW-2 stated that executive management was very hands-on and that Salmon attended monthly internal meetings commonly referred to as "product review meetings."

111. But rather than publicly come clean about the problems with the MiniMed 600 Series pumps, the tens of thousands of consumer complaints related thereto, the related quality control issues at the MiniMed Facility, and their impact on approval for the 780G in the United States, the Scheme Defendants concealed these issues through artifices and a deceptive course of business. Under the Scheme Defendants' leadership, the Diabetes Group publicized misleading studies touting the 670G in a falsely positive light and manipulated risk management protocols to artificially reduce the probability of occurrence of harm. And in one of Salmon's first moves as the head of the group, the Diabetes Group initiated a silent, partial recall of defective pumps ***one month*** after taking the helm. Because of their admitted close oversight over every aspect of the Diabetes Group, Hakami and Salmon were aware of the retainer ring defect, customer complaints, cybersecurity vulnerabilities, the MiniMed Facility's failure to comply with regulations, and the controlled studies. Further, Salmon

was aware of the FDA recall, the MiniMed Facility inspection, the Form 483, and Defendants' efforts to remediate the Form 483 issues. *See* §§VIII.A., VIII.C.3., *infra*.

2. Hakami and Salmon Were Motivated to Mislead the Market Regarding the Quality Issues in the MiniMed 600 Series to Buy Time Until the FDA's Approval of the MiniMed 780G

112. The FDA's approval of the MiniMed 780G insulin pump was a prerequisite to launching that product in the United States, which was vital to Medtronic regaining its leadership and market share in the diabetes market. Indeed, Hakami acknowledged at the June 9, 2019 Investor and Analyst Briefing from ADA that "we're sort of off cycle from an innovation standpoint in the U.S. That's just a fact, all right? So the 670G is going to be 3 years old in September in the United States." To secure the FDA's approval of the MiniMed 780G pump, the Scheme Defendants were motivated to mislead the market when detailing the scope and seriousness of the quality problems with Medtronic's prior insulin pumps and at the MiniMed Facility because those deficiencies directly impacted the FDA's approval of the 780G.

113. Having seen the MiniMed 600 Series problems and stagnating sales, Defendants introduced the MiniMed 780G pump, which they repeatedly pointed to as a growth driver. For example, Salmon stated on a February 18, 2020 earnings call: "***The 780G is an important catalyst for us to drive growth***." When discussing "reinvigorating this diabetes business" on June 12, 2020, Salmon asserted that "this reinvigoration, ***really it starts with 780G***."

114. With the MiniMed 780G pump's launch in Europe in June 2020, Medtronic and Salmon reported the positive patient response and their drive to achieve the same results in the United States. For example, Salmon stated during the February 23, 2021 Q3 2021 earnings call:

> So I'd say with 780G, what people are really enjoying about that is getting to stay in auto mode a lot longer. So that leads to better glycemic control. With the early reports, people are in the kind of the '90s in the post-market realm for glycemic control, but more importantly, they're not getting interrupted to take blood sugars that's cut down in half. They're able to sleep through the night with really good blood sugar control. And we measure things like Net Promoter Score on a product level as well, and it's up about tenfold from what we saw experience of 670G. So a very, very big improvement.
>
> And we're also seeing in the 670G, I think the transmitter, which connects CGM to the pump, seems to function better than the way we used to connect that on 670G. So it's more reliable. And that, coupled with being able to see your numbers in the phone, has led to a better experience as well. And of course, that pipeline is upgradable to not just the 780G, but also the new sensor pipeline you asked about and the extended wear infusion set.

115. With the message that the MiniMed 780G pump was needed in order to resuscitate the Diabetes Group and drive revenue growth, particularly after strong results were posted in Europe, the Scheme Defendants were motivated to mislead investors and regulators about the mounting quality and facility-level deficiencies that imperiled approval of the MiniMed 780G.

3. Hakami's Termination Supports Scienter

116. On October 19, 2019, as the longstanding quality defects with the MiniMed 600 Series pumps reached a breaking point – and shortly before the Class I recall of these devices was finally announced – Hakami was terminated. This occurred just prior to the November 2019 Field Safety Notification, which disclosed the MiniMed problems for the

first time (albeit incompletely). As Martha later explained: "[W]e've made some changes in Diabetes and that leadership team and a few other spots where we felt like we really needed to make those change[s]." Market analysts commented on Hakami's abrupt departure, attributing it to the Diabetes Group's underperformance and the need for a turnaround. An analyst at Morgan Stanley commented on October 21, 2019, "Salmon replaces Hooman Hakami . . . . Group leadership changes at Medtronic are rare . . . ." The report considered the replacement "necessary" for Medtronic to "execute the [business] plan that's on the table." Similarly, an analyst at Barclays commented on October 21, 2019, "[g]iven Diabetes missteps in the past, not surprising to see a change in leadership."

4. Hakami's and Salmon's Insider Sales Strongly Support Scienter

117. ***Hakami***. Hakami cashed out almost all of his Medtronic holdings – nearly 82% – before leaving the Company on October 21, 2019, with less than six years at the Company and as scrutiny over the Diabetes Group was intensifying. Hakami's stock sales on June 12, 2019 for proceeds of over $5.1 million and on September 10, 2019 for proceeds of nearly $9 million were expediently and suspiciously timed because shortly thereafter, on November 21, 2019, the increased complaints concerning the MiniMed 600 Series led Medtronic to issue a safety notification concerning the MiniMed 600 Series with a clear retainer ring (albeit one that failed to notify users of the full extent of the problems, much less the systemic quality and control deficiencies at the MiniMed Facility). Shortly thereafter, in February 2020, the FDA classified the notification as a Class 1 recall, causing

Medtronic's stock price to decline. Fortunately for Hakami, his sales preceded that stock decline.

118. Hakami was the President of the Diabetes Group for the first four months of the Class Period. His insider sales of more than ***$14 million*** during that four-month period are extremely unusual in amount as compared to the four months preceding the beginning of the Class Period – ***a period in which Hakami sold no stock***. In fact, prior to Hakami's outsized Class Period sales, Hakami had not sold any stock whatsoever since August 2018, when he sold only approximately $2.5 million of stock. Hakami's outsized sales bringing in proceeds of $5.1 million and $8.9 million on June 12, 2019 and September 10, 2019, respectively, were also notable for their proximity to the mounting problems in advance of Hakami's departure.

119. As Hakami began his exit from his Medtronic, analysts questioned the Diabetes Group's performance, noting on May 29, 2019, for example, that the business had "slowed"; on June 10, 2019, that it "struggled"; and on August 20, 2019, that the Company had "switched the guidance to the low end of the range" for the Diabetes Group. Yet Defendants maintained an upbeat message about Medtronic's upcoming pipeline, with Hakami emphasizing, for instance, on August 20, 2019 that the "pipeline . . . remains on track." On June 9, 2019, just days before Hakami's first Class Period sale, he deflected concerns regarding quarter-to-quarter "lumpiness" in the Diabetes Group, and assured investors that "670G is going to be ramping up even more in FY '20." When asked point blank by an analyst, "what's impacting your business negatively right now, most?" and whether "it [was] more 670G dynamics," Hakami suggested that increased competition after

three years on the market was a headwind, but withheld all details of the increasing numbers of customer complaints concerning the damaged pumps and retainer rings. Rather, Hakami suggested deceptively that Medtronic was facing "dynamics that . . . all of the pump companies are dealing with."

120. ***The next day***, Hakami sold $5.1 million of his Medtronic shares. Then, with the defective MiniMed 600 Series requiring a redesign and reissuance starting in August 2019, after Medtronic had received tens of thousands of complaints and masked the need to issue a recall by engaging in flawed risk assessments, Hakami sold on September 10, 2019 another almost $9 million of his Medtronic shares, bringing his total profits from insider selling to $5.7 million in less than three months.

121. ***Salmon***. On August 25, 2021, in insider trades executed on a ***single day, outside of a Rule 10b5-1 trading plan***, Salmon dumped almost half of his Medtronic holdings for proceeds of $3.8 million, raking in a one-day profit of $2.7 million, when Medtronic's stock price was trading near its Class Period high. Beyond the extraordinary size, amount, and impeccable timing, the sale was unusual because Salmon had not sold ***any*** shares in the three years preceding the Class Period. Additionally, the timing of Salmon's August 25, 2021 insider sales are incredibly suspicious because they were made ***the day after*** Salmon personally made misrepresentations concerning the approval of the MiniMed 780G, and ***not*** pursuant to a predetermined trading plan. The timing of Salmon's sales was also suspicious because they closely followed the FDA's inspection of the MiniMed Facility, and occurred during the period that he personally struggled to address the numerous severe

problems identified by the FDA in the form of multiple letters to the FDA authored and signed by Salmon himself.

VIII. RULE 10b-5(b) MISREPRESENTATION AND OMISSION CLAIM

A. Misrepresentations and Omissions Concerning Defendants' Interactions with the FDA, Approval of the MiniMed 780G Pump, Regulatory Compliance, and Facility Quality

122. Beginning on August 24, 2021, Martha and Salmon uttered classic half-truths and concealed information concerning their recent interactions with the FDA and the status of the 780G approval process, creating the impression that they were having "very positive" interactions with the FDA and that the Diabetes Group was making "good progress" and "excellent progress" on the 780G approval process. In truth, when Martha and Salmon spoke, they omitted the full story – that their recent interactions with the FDA were decidedly negative and the approval process was jeopardized due to known, widespread, and serious deficiencies impacting the MiniMed Facility. Defendants also made misleading statements and omissions concerning Medtronic's regulatory compliance and facility quality.

123. As a follow-up to the Class I recall of the 670G and the other 600 Series insulin pumps, the FDA conducted an inspection at the MiniMed Facility from June 7, 2021 to July 7, 2021. That inspection identified widespread deficiencies that were memorialized by the FDA on a Form 483, which, based on their severity, would take a year or longer to remediate. *See* Lavin Decl., ¶15. Moreover, the 780G would not be approved until these fundamental deficiencies at the MiniMed Facility responsible for manufacturing the 780G were remediated to the FDA's satisfaction. *Id.*, ¶16.

124. A Form 483 "does not include observations of questionable or unknown significance at the time of the inspection."[9] Rather, "FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and ***significant***."[10] In other words, FDA inspectors note only obvious "objectionable conditions" on the Form 483, but can raise additional, more "questionable" issues in the Management Discussion topics. *See also* Lavin Decl., ¶10 ("The Form 483 must be presented to the owner, operator, or agent in charge of the inspected facility and it must include the observations of conditions or practices which, in the FDA inspector's judgment, indicate that a device 'may have been rendered injurious to health.'"). The FDA then considers these "objectionable conditions" identified on the Form 483, as well as information in "a written report called an Establishment Inspection Report, all evidence or documentation collected on-site, and any responses made by the company" to determine what further regulatory action – such as a warning letter – is necessary to protect public health.

125. The July 7, 2021 Form 483 was the result of an inspection by Janet Pulver, MS, CMQ/OE, CSSGB, CQA, RAC, CTBS, the FDA's Division 3 Medical Device Senior Operations Officer. Ms. Pulver is a medical device expert with over 30 years of experience, including 15 years as an FDA Medical Device Investigator.[11] Ms. Pulver has conducted

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[9] FDA Form 483 Frequently Asked Questions. https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions.

[10] *Id*.

[11] https://www.linkedin.com/in/janet-pulver-ms-cmq-oe-cssgb-cqa-rac-ctbs-b541a0146/.

more than 200 FDA medical device inspections.[12] Ms. Pulver has been an advisor and instructor for multiple national FDA training courses, and was the recipient of the FDA's prestigious Patrick J. Pouzar, Investigator of the Year award in 2019.[13]

126. The Form 483 identified three categories of process- and facility-based deficiencies detailing where the Diabetes Group failed to: (1) have adequate procedures established to correct and prevent patient harm, including failing to appropriately quantify the risk of harm caused by the retainer rings in the 600 Series and failing to take action in a "timely manner" after receiving complaints to recall the defective products and prevent patient deaths and serious injuries; (2) appropriately investigate the life-threatening health consequences caused by the defective retainer rings; and (3) submit written reports to the FDA regarding the retainer ring defect and the resulting injuries and death. *See also* Lavin Decl., ¶¶11(a)-(c) (detailing the Form 483's three categories of systemic, facility-level deficiencies). These topics and two additional "Management Discussion topics" were discussed between the FDA and the Diabetes Group senior management during a "closing meeting" on July 7, 2021.

127. The "objectionable conditions" identified were far from minor or easily fixed. Rather, they detailed fundamental failures to assess, address, and prevent catastrophic health consequences suffered by users of the Diabetes Group's insulin pumps. *See* Lavin Decl., ¶15 ("Unlike a lab that simply required more detailed cleaning or missing equipment servicing records, based on my knowledge and decades of relevant experience, these deficiencies were

[12] *Id.*; *see also* https://ocra-dg.org/speaker/janet-pulver/.

[13] *Id.*

not easily or quickly fixed. Rather, these deficiencies implicated an entrenched lack of adequate safety and compliance procedures that were necessary to ensure that device defects and complaints arising from devices coming out of the Northridge facility were adequately investigated, remediated, and reported to the FDA."). Given the breadth and severity of the observations, resolving the systemic deficiencies would take considerable time – as CW-2 correctly adjudged, approximately one to two years. *See also id.* ("In my opinion, these systemic, pervasive deficiencies could not reasonably be remediated and cleared by the FDA in a matter of weeks or months. Rather, in my experience, these fundamental deficiencies, which implicated the Northridge facility as a whole, required protracted remediation efforts that could take a year or more to complete, document, and verify for effectiveness."). Indeed, Medtronic itself characterized the required remediation as "***broad, systemic***" and "***extensive***."

128. Moreover, while these failures were made evident to the FDA as a result of an inspection that occurred because of problems with the 600 Series pump, the deficiencies were not confined to those pumps. Rather, the deficiencies broadly concerned systemic problems with the Diabetes Group's procedures for addressing patient complaints, analyzing risk of catastrophic harm, investigating reported defects, notifying the public of dangerous defects, and issuing appropriate recalls of a malfunctioning product. These systemic issues necessarily meant that any related product under FDA review – including the 780G – would be stalled until the FDA was satisfied that the MiniMed Facility had remediated these deficient procedures. *See id.*, ¶16 ("Because these deficiencies concerned facility-wide issues that implicated the Northridge facility's ability to monitor, remediate, and report

product defects leading to potential severe patient injury and death, it is my opinion that FDA approval of the MiniMed 780G and any other new device coming out of the Northridge facility would be necessarily stalled from when those defects were identified by the FDA until the deficiencies were remediated, documented, and tested for effectiveness to the FDA's satisfaction."). Indeed, if the MiniMed Facility did not have adequate systems and procedures in place to respond to patient complaints for the 600 Series, such systems would necessarily be insufficient to address any similar complaints with respect to Medtronic's next generation insulin pump, as the MiniMed Facility was responsible for "manag[ing] customer complaint handling, recalls, medical device reporting, and design controls for the entire Diabetes [Operating Unit]."

129. Three weeks after receiving the Form 483, Salmon and Tilara sent their first letter response, dated July 28, 2021. The letter noted that the FDA's Form 483 was "issued to Medtronic MiniMed, Northridge, CA facility" and acknowledged that the remediation required to rectify the deficiencies required "***broad, systemic actions***." Anticipating a lengthy process in resolving the issues raised in the Form 483, including hiring an outside quality consultant, Salmon and Tilara told the FDA that the Diabetes Group would "provide periodic updates on the progress of [their] actions," with a "first update" to "be submitted by September 3, 2021." The letter also provided the FDA an appendix identifying numerous "action items," spanning 68 pages, which the Diabetes Group privately recognized was necessary to remediate the deficiencies observed by the FDA. As of this initial response, the Diabetes Group expected that some of their remediation measures could take until at least January 31, 2022, not including the many months thereafter required to document the

remediation, test for effectiveness, and present to the FDA for its sign-off. *See also* Lavin Decl., ¶¶17(a)-(c).

1. August 24, 2021

130. As Defendants began addressing the "extensive" remediation required within the Diabetes Group and in the midst of preparing for their next update to the FDA on September 3, 2021, Medtronic issued its Q1 2022 results on Form 8-K on August 24, 2021. In the press release, Medtronic touted the "strong growth" of the MiniMed 780G system in international markets, reiterated revenue growth guidance, and raised the lower end of its EPS guidance range for FY22.

131. Defendants also held an earnings conference call on August 24, 2021, led by Martha, Parkhill, and Salmon, in conjunction with reporting Medtronic's Q1 2022 financial results. At this point, the Diabetes Group had endured the FDA's month-long inspection, received the Form 483 detailing MiniMed Facility's systemic problems, and only just begun the "broad, systemic" remediation measures necessary to resolve the issues. All of these new circumstances adversely impacted Defendants' recent dealings with the FDA and jeopardized the 780G's approval within the near-term timeframe that the market had come to expect as a result of Defendants' prior statements.

132. Despite these adverse circumstances, Martha's prepared remarks regarding the 780G during the earnings call ***did not change***. During the prior quarter's earnings call, Martha touted the success of 780G in Europe and stated that the 780G was "under active review with the FDA." On the August 24, 2021 call, he repeated the exact same phrase, with no acknowledgement of the markedly negative circumstances that had arisen in the interim.

133. Salmon took it a step further in the Q&A session with analysts when he described the Company's interactions with the FDA regarding the 780G as "***really good***" and assured investors that "things are ***on track*** as far as we can tell." And he further affirmed that "we do think [we're] making ***good progress*** in [the review]." In response to a direct question by an analyst regarding the FDA's review of the 780G, Salmon stated:

> **Statement No. 1**[14] – [Salmon:] . . . The combination of 780G with the sensor that doesn't require confirmation, call it non-adjunctive, has been filed in the United States and ***we're seeing really good interactive back and forth review so that's really good***. But that Europe launch right in the second quarter where you have a no finger stick sensor mixed with an infusion set and 780G. It's really a nice combination. Of course, we'd love to bring that to the U.S. as soon as possible. ***But things are on track as far as we can tell. As you may know, that division of FDA has been very busy with COVID***, so it's hard to handicap exactly when time lines happen. ***But we do think we're making good progress in the review***.[15]

This statement was a classic half-truth – it was misleading to create the impression that the review process was "really good" when, unbeknownst to investors, the MiniMed Facility was out of compliance, resulting in a stalled approval process for all related products pending FDA approval out of that facility, including the 780G (which was, after all, seeking supplemental approval to the PMA for the 670G pump that was a primary source of the deficiencies leading to the Form 483). Further, the "interactive back and forth" with the

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[14] The specific statements alleged to be false or misleading by omission in violation of Rule 10b5-1(b) are identified herein as "Statement No. __." Statements referenced herein that are not designated as "Statement No. __" provide context to the specifically alleged misrepresentations.

[15] Due to third-party transcription errors and the third party transcriber's inability to discern certain portions of this statement, the quote above is based upon the undersigned's review of the audio recording of the August 24, 2021 conference call, available at: https://player.vimeo.com/video/576774322?badge=0&autopause=0&player_id=0&app_id=58479&h=149cbfd246%22.

FDA was not "really good" nor was the review making "good progress." To the contrary, the interactions with the FDA immediately preceding this statement were indisputably negative and the review was stalled – the FDA had conducted a month-long inspection, identified widespread, fundamental deficiencies at the MiniMed Facility in a Form 483 and closing meeting, and had received Salmon's July 28, 2021 letter describing the "broad, systemic" remediation that Medtronic had barely just begun. These deficiencies would take a year or longer to remediate, document, test for effectiveness, and present to the FDA. *See* Lavin Decl., ¶18.

134. That same day, on August 24, 2021, Martha gave an interview with *Bloomberg TV* after the earnings call.[16] Martha discussed the Diabetes Group's pipeline of products awaiting FDA approval, including the 780G, misleadingly attributed any delay to the FDA being "very busy with Covid and a few other things," and stated that "the conversations we're having with them [the FDA] have been ***very positive*** on Diabetes approvals":

> **Statement No. 2** – [Martha:] [W]e have a very rich pipeline of new pumps, new sensors, new continuous glucose monitoring sensors, new infusion sets that are used to deliver the insulin from you know into the body and even new form factors. We've got a new smart pen. So we've got a great pipeline of products actually on the market in Europe and growing very well and taking share. And ***we just got to get those products from Europe approved here in the United States. And the FDA has been very busy with COVID and a few other things. But the conversations we're having with them have been very positive on Diabetes approvals***.

The opposite was true – at the time Martha spoke, Medtronic's conversations were anything but positive. These misrepresentations falsely reassured investors that the process had not

[16] Medtronic CEO on Earnings, Return to Office, Competition, *available at* https://www.bloomberg.com/news/videos/2021-08-24/medtronic-ceo-on-earnings-return-to-office-competition-video.

stalled and an approval during FY22 was forthcoming. In truth, the FDA would not approve 780G until after the deficiencies were remediated. *See* Lavin Decl., ¶16. And given the breadth of the deficiencies, they would not be remediated by the end of the calendar year or even April 2022 (the timeline the market expected based on Defendants' statements). *Id.*, ¶15.

135. The very next day, on August 25, 2021, Martha sold 11,581 shares for proceeds of $1.5 million.

136. Salmon also sold that same day, selling 28,419 shares for proceeds of $3.8 million.

137. Based on Martha's and Salmon's August 24, 2021 statements, the market continued to believe that the 780G would be approved by the end of 2021 or by April 2022 at the latest. For example, an August 24, 2021 Barclays report stated, "780G and the G4 sensor are now being actively reviewed by the FDA, which, in our view, ***means approval could come before the end of this calendar year***." An August 24, 2021 Bank of America report stated, "US Approval of 780G . . . . Under 'active review' with FDA as of late May 2021, ***we anticipate approval in CY21***," and Jefferies analysts stated that "the launch of the 780G/Guardian 4 in the EU and ***FDA approval likely in FY'22***." An August 24, 2021 J.P. Morgan analyst report stated, "780G pump remains under active review at the FDA with the ***hope of an approval in 2021***." An August 25, 2021 Deutsche Bank analyst report stated that "FDA approval of 780" was "***likely within the next couple quarters***." And an August 25, 2021 Morgan Stanley analyst report stated, "780G is currently under active FDA review,

with approval timelines still hard to pinpoint; ***management does view approval prior to year-end 2021 as realistic***."

138. Similarly, because Defendants attributed the delay in obtaining FDA approval to COVID (rather than the systemic "objectionable conditions" observed by the FDA at the MiniMed Facility), analysts, unaware of the truth, echoed Defendants' COVID excuse and continued to believe Defendants' message that the review process was making positive progress. For example, an August 24, 2021 Cowen analyst report stated that the Company "called the FDA review process active, which is modestly encouraging given the regulatory bottlenecks created by COVID-19." And an August 24, 2021 William Blair analyst report noted that the Company "was in an active review process with the FDA for its 780[G]," and while "[m]ost diabetes FDA submissions have faced delays this year," "it appears that there is some traction being made again."

2. September 1, 2021

139. One week after the earnings call and two days before submitting the second letter response to the FDA, Martha spoke on a September 1, 2021 podcast posted on Medtronic's website.[17] Martha touted the success of 780G in Europe and emphasized, "[w]e just need to get that [approved] in the U.S." to boost the financial performance of the Diabetes Group. Martha also said that the FDA was "pretty busy with Covid," making it "hard to handicap" when to expect the 780G's approval, but reiterated that "we're in active dialogue with them on these approvals with our pump and new sensor":

[17] https://news.medtronic.com/medtronictalks-podcast-geoff-martha-q1-earnings.

> **Statement No. 3** – [Martha:] ***The FDA that handles that approval's been pretty busy with COVID*** and it's hard to handicap and approve it, ***but we're [in] active dialogue with them on these approvals with our pump*** and new sensor and various other things.

140. Thus, sticking to the Company's go-to description of the "active" approval process, Martha continued to tell only half of the story. In truth, although the 780G application remained pending, the FDA's dialogue with the Diabetes Group was now focused on addressing the widespread deficiencies in the Form 483, which would prevent the approval of 780G until they were remediated. *See* Lavin Decl., ¶16.

141. On September 3, 2021, Salmon sent the FDA his second letter providing an update response to the FDA regarding the Form 483. It included actions the Diabetes Group had taken to attempt to address the FDA's observation, as well as numerous actions still to complete. The letter identified numerous planned but incomplete remediation efforts, and estimated that some would not be completed until January 31, 2022 at the earliest. *See id.*, ¶¶17(a)-(c). But even if the Diabetes Group was able to meet the "optimistic" completion dates, "it would take many months after completion for the FDA to review the remediation efforts, review the voluminous documentation describing the efforts, and verify that the corrective actions were effective." *Id.*, ¶19.

142. On October 5, 2021, Medtronic issued a full recall of any 600 Series insulin pumps that had a clear retainer ring. Noting that it had "first communicated about this recall in November 2019 with instructions to examine your pump for potential retainer ring damage and instructions to contact us if the retainer ring appeared to be loose, damaged or missing," Medtronic was now "updating this recall to ***replace*** any MiniMed 600 series

insulin pump that has a clear retainer ring with a MiniMed 600 series insulin pump that has the updated black retainer ring design" (emphasis in original).

143. This action was taken in response to the FDA's issuance of the Form 483. However, the market still remained unaware of the month-long inspection, the Form 483, and the "extensive" remediation that Medtronic needed to undertake, which had upended the prospects for the 780G's approval during FY22.

144. Salmon sent his third letter to the FDA regarding the Diabetes Group deficiencies on October 8, 2021. In it, Salmon reported, among other updates, that the Diabetes Group had "[c]ompleted an assessment of the complaint investigation and post market surveillance process to strengthen the depth and rigor of complaint investigations." Salmon claimed that this review determined that actions taken so far by the Diabetes Group in response to the Form 483 would "appropriately strengthen the overall depth and rigor of Complaint Investigations." Yet, Salmon conceded that the review also "determined that there are additional opportunities to improve." The letter identified numerous planned but incomplete remediation efforts, and estimated that some would not be completed until January 31, 2022 at the earliest. *See* Lavin Decl., ¶17(c). But even if the Diabetes Group was able to meet the "optimistic" completion dates, "it would take many months after completion for the FDA to review the remediation efforts, review the voluminous documentation describing the efforts, and verify that the corrective actions were effective." *Id.*, ¶19. The letter also referred to corrective actions related to "Complaint Investigations" that were incomplete and did not have an estimated completion date. *Id.*, ¶17(c).

3. October 12, 2021

145. On October 12, 2021, Medtronic issued a press release announcing the release of its FY 2021 Integrated Performance Report.[18] Martha was quoted in the press release and also highlighted the release of the report at an investor conference the following day. In the opening pages of the Integrated Performance Report, Martha and Parkhill each addressed Medtronic investors in "Letters to our stakeholders." Within a section of the report detailing "patient safety and product quality," Martha and Parkhill stated and/or authorized the Company to state that Medtronic was in compliance with FDA regulations:

> **Statement No. 4** – [Medtronic, Martha, and Parkhill:] ***We adhere to regulatory requirements, such as those set by the U.S. FDA, and we update our procedures in line with emerging regulations and standards***.

This statement was misleading because, at the time it was made, Medtronic was not in compliance with and had not adhered to regulatory requirements. Rather, in the July 7, 2021 Form 483, the FDA had identified severe and pervasive objectionable conditions relating to the Diabetes Group's failure to adhere to FDA regulations governing required procedures for corrective and preventative action, complaint investigation, and regulatory submissions.

146. The FY 2021 Integrated Performance Report also included updates regarding Medtronic's "facility quality and compliance." The Company described that "formal oversight of quality ultimately sits with our board and executive leadership" and noted that "our chief quality officer sits on the executive committee and reports directly to the CEO on all quality matters." In describing how the Company evaluated its progress with respect to

[18] https://www.medtronic.com/content/dam/medtronic-wide/public/brand-corporate-assets/resources/2021-integrated-report_corpmark_mdt.pdf.

facility quality and compliance, Defendants described that "inspections by regulatory agencies play an essential role in our sector." Defendants went on to describe the purported improvement in Medtronic's facility quality and compliance, stating:

> **Statement No. 5** – [Medtronic:] Facility quality and compliance. . . . In FY21, we received an average of . . . 0.02 findings per U.S. Food and Drug Administration (FDA) inspection – continuing to demonstrate year-on-year improvements.

It was misleading to tout facility quality and compliance when, at the same time, the MiniMed Facility had suffered a damning inspection and received a lengthy Form 483 requiring extensive, protracted remediation.

147. Salmon sent the fourth update letter to the FDA on November 5, 2021. In it, Salmon identified numerous planned but incomplete remediation efforts, and now estimated that some would not be completed until June 24, 2022 at the earliest. *See also* Lavin Decl., ¶17(d). But even if the Diabetes Group was able to meet the "optimistic" completion dates, "it would take many months after completion for the FDA to review the remediation efforts, review the voluminous documentation describing the efforts, and verify that the corrective actions were effective." *Id.*, ¶19. The letter also referred to remediation plans and complaint investigation corrective actions that were incomplete and did not have an estimated completion date. *Id.*, ¶17(d).

148. At this time, analysts and the market remained in the dark that the FDA had observed pervasive deficiencies at the MiniMed Facility. Thus, analysts still reported their expectation – based on Defendants' statements – that the 780G would be approved in the near-term. For example, as of October 13, 2021, BTIG reported "4Q21 – Expected US FDA

clearance for 780G in the US" while on November 19, 2021, in a nod to the late calendar date, a Morgan Stanley analyst reported that the 780G's approval was "increasingly looking like a 1HCY22 [first half calendar-year 2022] event."

4. November 23, 2021

149. On November 23, 2021, Medtronic issued its Q2 2022 results on Form 8-K. In the press release, Medtronic highlighted "[s]trong pump sales," including from sales of the MiniMed 780G system in international markets, but lowered guidance, blaming "the greater-than-expected market impact of the pandemic and healthcare system staffing challenges . . . ." During a conference call held the same day, attended by Martha, Parkhill, and Salmon, Martha repeated his mantra that the 780G was "under active review with the FDA," while assuring investors that "our diabetes turnaround is coming." When an analyst asked Salmon about the timing of the 780G's approval, Salmon responded that the market should expect "nothing different" and took it a step further, stating that Defendants have "had very good interactive conversations with [the] FDA":

> **Statement No. 6** – [Salmon:] . . . Yes, Larry, so ***nothing different than what we've been talking about all along***. We've got really strong uptake of 780G and Guardians 4 Sensor outside the United States. In the U.S., we have just – we're waiting for that approval to come through, and ***we've had very good interactive conversations with FDA***. I think ***we're making excellent progress there***.

150. Again, the opposite was true. Far from "nothing different," the 780G could not be approved until the extensive remediation efforts were completed, documented, checked for effectiveness, and confirmed by the FDA. *See* Lavin Decl., ¶16. These efforts would take a year or longer from the time they were identified in July 2021, meaning that 780G would not be approved by April 2022, as Defendants led the market to believe. *Id.*, ¶15.

Moreover, Defendants' conversations with the FDA leading up to Salmon's November 23, 2021 statement were anything but "very good" – they concerned extremely negative issues related to the inspection, the Form 483, and Salmon's unsuccessful attempts to convince the FDA that the MiniMed Facility had resolved its many deficiencies. (By this date Salmon had sent letters to the FDA on July 28, 2021, September 3, 2021, October 8, 2021, and November 5, 2021. There is no evidence that during this period the FDA agreed that any of Medtronic's proposed remediation efforts were effective.).

151. Defendants' positive statements continued to deceive the market. A November 23, 2021 Piper Sandler analyst report stated that Medtronic's "diabetes franchise is improving a bit and new products are coming (namely 780G in '22)." The Piper Sandler analysts report further stated that the 780G "remains tied up with the FDA (though conversations with the agency ***seem to be progressing***)." A November 23, 2021 UBS analyst report repeated Salmon's falsehood, parroting that Medtronic was "having ***good conversations with the FDA***" related to the 780G. A November 24, 2021 Morgan Stanley analyst report reiterated that the 780G "remain[ed] in active review with the FDA, with approval increasingly looking like a 1HCY22 [first half calendar year 2022] event." A November 23, 2021 BTIG analyst wrote that FDA approval of the 780G was expected in 4Q21 of the calendar year (as opposed to Medtronic's fiscal year), and a November 27, 2021 Morningstar analyst report stated that "we anticipate FDA approval on the 780g pump" in "***spring 2022***." And demonstrating the importance that the market placed on the term, at least seven analysts reported on the FDA's purported "active" review of the 780G following the Q2 2022 earnings announcement, establishing that Martha's and Salmon's half-truths

succeeded in convincing the market that nothing had negatively impacted Defendants' interactions with the FDA or the 780G's approval process.

152. Less than ten days later, Salmon sent his fifth and final letter to the FDA, dated December 3, 2021. In it, Salmon identified numerous planned but incomplete remediation efforts, and estimated that some would not be completed until January 14, 2023 at the earliest (including an October 28, 2022 target date to reassess complaints characterized as "Catastrophic, Critical, Major"). *See also* Lavin Decl., ¶17(e). But even if the Diabetes Group was able to meet these "optimistic" completion dates, "it would take many months after completion for the FDA to review the remediation efforts, review the voluminous documentation describing the efforts, and verify that the corrective actions were effective." *Id.*, ¶19. The letter also referred to remediation plans and complaint investigation corrective actions that were incomplete and did not have an estimated completion date.

153. On December 9, 2021, the FDA issued a Warning Letter concerning pervasive deficiencies arising from the Diabetes Group's failure to take corrective and preventive action in response to serious health consequences when patients used defective MiniMed insulin pumps, failure to properly investigate patient complaints, and failure to timely inform the FDA of dangerous product defects. The FDA stated that the Diabetes Group's responses to the Form 483 were "***not adequate***" and noted that several corrective actions were "not complete." *See also* Lavin Decl., ¶20 ("Consistent with my understanding of the protracted nature of the remediation required by the deficiencies presented in the Form 483, the Warning Letter cited the Northridge facility's failure to provide 'evidence of implementation for all corrections and corrective actions' and stated, 'your corrective actions are still in

process, and you have not yet conducted effectiveness checks to ensure the updated procedures and required employee training will prevent reoccurrence of the identified deficiencies.'"). The FDA directed Medtronic to provide "specific steps your firm has taken to correct the noted Quality System and MDR reporting deficiencies, as well as an explanation of how your firm plans to prevent these deficiencies or similar deficiencies from occurring again" and noted that the corrections "must address ***systemic problems***." Unsurprisingly, the FDA stated that "premarket approval applications for Class III devices to which the Quality System regulation deficiencies are reasonably related will not be approved until the deficiencies have been corrected."

154. Defendants' misrepresentations, half-truths, and omissions regarding their interactions with the FDA, the current status of the FDA's review of 780G, Medtronic's facility quality, and Medtronic's regulatory compliance, as set forth in ¶¶133-134, 139, 145-146, and 149, *supra*, were materially misleading and omitted material facts necessary to render the statements made not misleading for the following reasons:

(a) Just prior to making Statement Nos. 1-6, the MiniMed Facility had endured a month-long FDA inspection from June 7, 2021 to July 7, 2021, during which an FDA investigator with 30 years of experience (15 as an FDA Medical Device Inspector) and who has conducted more than 200 medical device inspections identified pervasive, process- and facility-based deficiencies related to systemic failures to: (i) take corrective and preventive actions after receiving complaints of product defects endangering patients; (ii) implement appropriate procedures to evaluate patient complaints and assess risk; (iii) properly investigate complaints; and (iv) inform the FDA of complaints related to

malfunctioning devices. "[T]hese fundamental deficiencies, which implicated the Northridge facility as a whole, required ***protracted remediation efforts that could take a year or more to complete, document, and verify for effectiveness***." Lavin Decl., ¶15. These circumstances rendered Statement Nos. 1-6 misleading, as a negative FDA inspection resulting in severe and pervasive Form 483 findings is inconsistent with "***good interactive back and forth***" with the FDA (Statement No. 1), inconsistent with "very positive" interactions (Statement No. 2) and "***very good interactive conversations***" with the FDA (Statement No. 6), and inconsistent with "***adher[ing] to regulatory requirements***" (Statement No. 4). Salmon even went so far as to state on November 23, 2021 – despite, by that point, having personally spent months attempting (unsuccessfully) to convince the FDA that Medtronic was making progress on the overwhelming deficiencies – that there was "***nothing different*** than what we've been talking about all along" with respect to the timing of 780G approval (Statement No. 6).

(b) Shortly before uttering Statement Nos. 1 and 2, Salmon and Martha had received the Form 483 memorializing the Diabetes Group's systemic failures to properly assess, investigate, and evaluate device defects and take appropriate action to prevent harm. Moreover, the systemic deficiencies implicated widespread failures at the MiniMed Facility responsible for manufacturing both the 670G and 780G devices, which implicated Medtronic's ability to obtain approval for any related device pending approval out of the MiniMed Facility. *See* Lavin Decl., ¶16 ("Because these deficiencies concerned facility-wide issues that implicated the Northridge facility's ability to monitor, remediate, and report product defects leading to potential severe patient injury and death, it is my opinion that ***FDA approval of the MiniMed 780G and any other new device coming out of the***

Northridge facility would be necessarily stalled from when those defects were identified by the FDA until the deficiencies were remediated, documented, and tested for effectiveness to the FDA's satisfaction.").

(c) Just prior to each of Statement Nos. 1-6, Salmon sent correspondence on behalf of Medtronic to the FDA acknowledging the "***broad, systemic actions***" required to address the pervasive and serious deficiencies contained in the Form 483, all of which: (i) painted a decidedly negative picture of Medtronic's dealings with the FDA; (ii) demonstrated that obtaining FDA approval by the date Defendants had led the market to believe (by April 2022 at the latest) was highly unlikely; and (iii) belied Defendants' statement that Medtronic was in compliance with applicable regulations. For example:

(i) Just prior to Statement Nos. 1 and 2 (made on August 24, 2021), Salmon sent his first of five letters to the FDA on July 28, 2021. "From the outset, the July 28 letter identified extensive actions to address each of the three observations in the FDA 483 concerning the risk management systems, complaint investigations, and MDR accuracy and timeliness. For example, Table 1 to the July 28 letter identifies 23 initial action items to support the resolution of these three major issues. In my opinion, ***these are time consuming activities which, collectively, would take a year or more to complete, document, test for effectiveness, and present to the FDA, not including FDA feedback and time to sign off on completed tasks***." Lavin Decl., ¶18. In fact, the July 28 letter outlined numerous required remediation activities, and Salmon privately estimated that all of the required work would not be completed until January 31, 2022 at the earliest. Moreover, the completion dates referenced in the July 28 letter were "optimistic," but "even if Medtronic had succeeded in

completing some or all of the required remediation by their estimated dates, it would take many months after completion for the FDA to review the remediation efforts, review the voluminous documentation describing the efforts, and verify that the corrective actions were effective." *Id.*, ¶19. Given this reality, and given the importance of a medical device company's statements about its dealings with the FDA, Salmon's and Martha's characterization of their interactions with the FDA as "***really good***" and "***very positive***" and their representations that they were "***making good progress in [the review]***" and that the review was "***on track***" (Statement Nos. 1-2) were misleading. Indeed, former Director of the SEC's Division of Enforcement Andrew Ceresney emphasized the importance of accuracy regarding communications with the FDA:

> One significant type of key event that we see causing problems with disclosure in your [device and pharmaceutical] industry is disclosures on your dealings with the FDA. ***Accuracy of reporting in your dealings with the FDA is critical to getting investors the information they need. FDA dealings and approvals are the lifeblood of your business and are so important to investment decisions***.[19]

(ii) Two days after Statement No. 3 (made on September 1, 2021), Salmon sent his second of five letters to the FDA on September 3, 2021. Like the July 28 letter, this letter also identified numerous required but incomplete remediation efforts, and Salmon privately estimated that all of the required work would not be completed until January 31, 2022 at the earliest. And even if Medtronic had achieved the "optimistic" completion dates, which are belied by the extent of the required remediation (*see* Lavin Decl., ¶17(b)), "it would take many months after completion for the FDA to review the

[19] https://www.sec.gov/news/speech/2015-spch030315ajc.

remediation efforts, review the voluminous documentation describing the efforts, and verify that the corrective actions were effective." *Id.*, ¶19. Thus, it was misleading for Martha to blame any delays on the FDA being "pretty busy with COVID" while omitting that the negative inspection, Form 483, and Medtronic's incomplete remediation efforts were causing delay.

(iii) Four days prior to Statement Nos. 4 and 5 (made on October 12, 2021), Salmon sent his third of five letters to the FDA on October 8, 2021. Like the July 28 and September 2 letters, this letter also identified numerous required but incomplete remediation efforts, Salmon privately estimated that all of the required work would not be completed until January 31, 2022 at the earliest. Additionally, Salmon evaded specifying any completion date for the remediation required to address the MiniMed Facility's "Complaint Investigations" – one of the primary deficiencies identified in the Form 483 – and purported to close that corrective action, stating that remediation would be "managed through the CAPA [Corrective Action and Preventative Action] process." *See also* Lavin Decl., ¶17(c). In other words, Salmon conspicuously did not provide a completion date for the remediation required to rectify Observation 1 on the FDA's Form 483 – that "[p]rocedures for corrective and preventive action have not been adequately established." Even if Medtronic had achieved the "optimistic" completion dates, which are belied by the extent of the required remediation (*see* Lavin Decl., ¶19), "it would take many months after completion for the FDA to review the remediation efforts, review the voluminous documentation describing the efforts, and verify that the corrective actions were effective." *Id.*, ¶17(c). Moreover, the Form 483 and Salmon's responses up to this point demonstrate

that the deficiencies identified on July 7, 2021 were "broad categories of systemic, facility-level deficiencies" that "implicated an entrenched lack of adequate safety and compliance procedures that were necessary to ensure that device defects and complaints arising from devices coming out of the Northridge facility were adequately investigated, remediated, and reported to the FDA." *Id.*, ¶15. The deficiencies also implicated violations of 21 C.F.R. §§803.50(a)(1), 820.100(a), and 820.198(c). *See* ¶¶99-103, *supra*. Given the severe and pervasive regulatory deficiencies and violations, Defendants' unequivocal statement that ***"[w]e adhere to regulatory requirements, such as those set by the U.S. FDA***" (Statement No. 4) was misleading. Similarly, it was misleading to cast Medtronic's "[f]acility quality and compliance" in an unequivocally positive light (Statement No. 5) when, in truth, the MiniMed Facility had just encountered a rare inspection resulting in an even rarer Form 483 identifying crippling deficiencies, all of which remained hidden from the market.

(iv) Two weeks prior to Statement No. 6 (made on November 23, 2021), Salmon sent his fourth of five letters to the FDA on November 5, 2021. Like the July 28, 2021, September 2, 2021, and October 8, 2021 letters, this letter also identified numerous required but incomplete remediation efforts that Salmon estimated would not be completed until June 24, 2022 at the earliest. And even if Medtronic had achieved the "optimistic" completion dates, which are belied by the extent of the required remediation (*see* Lavin Decl., ¶17(d)), "it would take many months after completion for the FDA to review the remediation efforts, review the voluminous documentation describing the efforts, and verify that the corrective actions were effective." *Id.*, ¶19. The letter "also referred to remediation plans and complaint investigation corrective actions that were incomplete and did not have

an estimated completion date." *Id.*, ¶17(e). By the time Salmon uttered Statement No. 6, Defendants had spent more than four months assessing the grave nature of the deficiencies and Salmon had spent months writing unsuccessful letters to the FDA. Despite the fully entrenched deficiencies, some of which Salmon now admitted would not be completed until June 24, 2022 (***not*** including necessary time for the FDA to review and approve the remediation efforts), Salmon stated that there was "***nothing different*** than what we've been talking about all along" relating to 780G approval, that "we've had ***very good interactive conversations with FDA***," and "we're ***making excellent progress*** there" (Statement No. 6). As discussed above, "[a]ccuracy of reporting in your dealings with the FDA is critical to getting investors the information they need. FDA dealings and approvals are the lifeblood of your business and are so important to investment decisions." ¶154(c)(i), *supra*.

(v) Just after Statement No. 6 (made on November 23, 2021), Salmon sent his fifth and final letter to the FDA on December 3, 2021. Like the July 28, 2021, September 2, 2021, October 8, 2021, and November 5, 2021 letters, this letter also identified numerous required but incomplete remediation efforts, certain of which Salmon estimated would not be completed until January 14, 2023 at the earliest. The letter "also referred to remediation plans and complaint investigation corrective actions that were incomplete and did not have an estimated completion date." *Id.*, ¶17(e). Six days later, the FDA issued the Warning Letter, which confirmed Medtronic's regulatory violations and made clear that the protracted and extensive remediation process had only just begun.

(d) Defendants had no reasonable basis to state that the 780G's review process with the FDA was "really good," "very positive," or "on track" given the month-long

inspection of the MiniMed Facility, the resulting Form 483 in which the FDA identified systemic deficiencies, the letter-writing campaign in which Salmon attempted (unsuccessfully) to respond to the Form 483 by detailing the admittedly extensive remediation that would be required to bring the facility back into compliance would not be completed for months into 2022 and even into 2023, and Salmon's and Martha's own recognition that remediation would be "broad, systemic" and "extensive." Nor did they have any reasonable basis to state that "nothing different" had occurred with respect to 780G approval, or that Medtronic "adhere[d] to regulatory requirements, such as those set by the U.S. FDA."

(e) Having elected to speak on their interactions with the FDA and the approval process for the 780G, Defendants were obligated to speak fully and truthfully on those issues. Defendants claimed that their interactions were positive and that the approval process was and proceeding on track, and that any delay was caused by COVID delays. Through classic half-truths that gave the good but not the bad, Defendants concealed that:(i) the FDA had identified severe, systemic deficiencies at the MiniMed Facility that imperiled new device approvals coming out of the facility until remedied; and (ii) Medtronic had only just begun "extensive" remediation that would take a year or longer to complete, test for effectiveness, and obtain FDA sign-off. By only raising COVID as a reason for the delay in the 780G's approval, Defendants gave the false impression that Defendants were aware of no other issues that could delay approval, despite their awareness of the FDA's month-long inspection, the Form 483, and the numerous actions necessary for the Diabetes Group to correct the problems.

(f) CW-2 explained that they attended monthly meetings between the FDA and Medtronic personnel in which the MiniMed 780G approval timeline was discussed, and that they also attended, along with Parkhill and Salmon, monthly internal meetings where the status of the MiniMed 780G application was discussed. CW-2 further explained that executive management closely monitored the progress of FDA approval for the MiniMed 780G product, remarking that "this was our live or die product" – an observation that is corroborated by Defendants' own repeated, detailed statements about the 780G device and its approval process.

(g) CW-2 stated that executive management was very hands-on and that "all developments in the Diabetes units were reported up the chain of command to the CEO."

(h) When CW-2 informed executive management that the MiniMed 780G had no chance of obtaining timely approval, they were told that "this information would not be disseminated to the public before the next analyst call, which was two weeks away." Because there are only two relevant quarterly analyst calls during the period relevant to Defendants' misrepresentations (Q1 2022, issued on August 24, 2021; and Q2 2022, issued on November 23, 2021), the inference is strong that CW-2 was told that the negative information would not be announced during either Medtronic's Q1 2022 or Q2 2022 quarterly earnings announcements. Similarly, CW-2 stated that "executive management did not clearly share MiniMed 780G's progress information with the public." CW-2 stated that executive management knew before receiving the Warning Letter that the MiniMed 780G would not receive timely approval, and that "executive management continued to communicate misinformation to the public" anyway.

B. Misrepresentations and Omissions Concerning Risk Warnings

155. On September 2, 2021, Medtronic issued its Q1 2022 financial results on Form 10-Q, signed by Martha and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's Annual Report on Form 10-K, including the following:

> **Statement No. 7**: [Medtronic, Martha, and Parkhill:] Both before and after a product is commercially released, ***we have ongoing responsibilities under the U.S. FDA*** and other applicable non-U.S. government agency regulations. For instance, ***many of our facilities and procedures and those of our suppliers are also subject to periodic inspections by the U.S. FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on the U.S. FDA's Form-483***, warning letters, or other forms of enforcement. ***If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations***, or that any of our medical products are ineffective or pose an unreasonable health risk, ***the U.S. FDA could*** ban such medical products, detain or seize adulterated or misbranded medical products, order a recall, repair, replacement, or refund of such products, ***refuse to grant pending pre-market approval applications or require certificates of non-U.S governments for exports***, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health.

156. On December 2, 2021, Medtronic issued its Q2 2022 financial results on Form 10-Q, signed by Martha and Parkhill. The Form 10-Q referred investors to the risk factors previously published in Medtronic's Annual Report on Form 10-K, including the following:

> **Statement No. 8**: [Medtronic, Martha, and Parkhill:] Both before and after a product is commercially released, ***we have ongoing responsibilities under the U.S. FDA*** and other applicable non-U.S. government agency regulations. For instance, ***many of our facilities and procedures and those of our suppliers are also subject to periodic inspections by the U.S. FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on the U.S. FDA's Form-483***, warning letters, or other forms of enforcement. ***If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations***, or that any of our medical products are ineffective or pose an unreasonable health risk, ***the U.S. FDA could*** ban such medical products, detain or seize adulterated or misbranded medical products, order a recall, repair, replacement, or refund of such products, ***refuse to grant pending pre-market***

> ***approval applications or require certificates of non-U.S governments for exports***, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health.

157. Defendants' statements and omissions purportedly warning of the risk that FDA inspections "can" lead to "inspectional observations on the U.S. FDA's Form-483," which in turn "could" lead to the FDA "refus[ing] to grant pending pre-market approval applications," as set forth in ¶¶155-156, *supra*, were materially misleading and omitted material facts necessary to render the statements made not misleading for the following reasons:

(a) Just prior to making Statement Nos. 7 and 8, the MiniMed Facility had endured a month-long FDA inspection from June 7, 2021 to July 7, 2021, during which an FDA investigator with 30 years of experience (15 as an FDA Medical Device Inspector) and who has conducted more than 200 medical device inspections identified pervasive, process- and facility-based deficiencies related to systemic failures to: (i) take corrective and preventive actions after receiving complaints of product defects endangering patients; (ii) implement appropriate procedures to evaluate patient complaints and assess risk; (iii) properly investigate complaints; and (iv) inform the FDA of complaints related to malfunctioning devices;

(b) Shortly before making Statement Nos. 7 and 8, Salmon and Martha had received the Form 483 memorializing the Diabetes Group's systemic failures to properly assess, investigate, and evaluate device defects and take appropriate action to prevent harm. Moreover, the systemic deficiencies implicated widespread failures at the MiniMed Facility responsible for manufacturing both the 670G and 780G devices, which implicated

Medtronic's ability to obtain approval for any related device pending approval out of the MiniMed Facility. *See* Lavin Decl., ¶16; and

(c) Accordingly, at the time Defendants warned of the potentiality that an inspection "can" lead to a Form 483, which in turn "could" lead to the FDA withholding approval of a PMA, Defendants were aware that these purported potentialities had already come to fruition.

C. Defendants Acted with Scienter

1. Defendants Admitted that the Product Quality Systems for the Diabetes Group Was a Longstanding Problem

158. As Medtronic reported in its December 15, 2021 press release, the FDA's "warning letter focus[ed] on the inadequacy of specific medical device quality system requirements at the Northridge facility in the areas of risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events." Yet, these issues were not suddenly made apparent to Defendants with the Warning Letter. Rather, as Martha admitted while participating on a January 10, 2022 conference call hosted by JP Morgan: "Improving the performance of our Diabetes business, ***including the quality system, is something that we've been working on for the past couple years***." During a February 22, 2022 earnings call, Martha reiterated that the Company had been working on the concealed problems in the Diabetes Group for two years:

> Our priority is – they're both priorities, but our first priority is to work the warning letter issues, and ***we've been working on these, like as we talked about, for 2 years now, even before the warning letter was issued***.

159. Thus, by their own admission, Defendants had internally recognized that the Diabetes Group's product quality systems had been underperforming for years.

2. Salmon's Regular Communication with the FDA Supports a Strong Inference of Scienter

160. Throughout the Class Period, Salmon emphasized his regular communications with the FDA, further supporting the inference that he knew that the issues at the MiniMed Facility were impacting the FDA's review and imperiling approval of the 780G by the end of FY22. For example, when discussing the timeline for the MiniMed 780G's submission to the FDA during the February 18, 2020 Q3 2020 earnings call, Salmon affirmed to investors: "We're very interactive with [the] FDA. In fact, we'll be meeting with them later this week."

161. Even during the COVID pandemic, Salmon pointed investors to his close working relationship with the FDA. For example, Salmon claimed on October 14, 2020 that the FDA's involvement in the COVID crisis was "good in some ways because ***we've been very collaborative*** about what the right kind of cadence is for filing" for FDA approval of the MiniMed 780G pump. And during the May 27, 2021 Q4 2021 earnings call, Salmon stated:

> We're in active review, as Geoff said, on the filing. And we – the reviewer that's working with us is the same one that reviewed the 770 device. So we think that, that familiarity is going to be helpful.

162. Salmon repeated the same message during a Q&A session at a June 2, 2021 Jefferies Healthcare Conference:

> And I think what's good for us is the FDA understands how important this product is. They're very sympathetic to that. We're in active review right now. The reviewer who's assigned to the 780G as well as the rest of the products to Zeus is the same one that was on the 770G. So the hardware is well known to this reviewer and the review team. It's really a question of the software or the upgrade path or over-the-air security, that kind of stuff. So we hope that there's a good glide path toward a smooth review. But they've really been prioritizing COVID, of course, over other things right now.

> But I mean good ***familiarity is always important. Good connections with those reviewers is important***.

163. As late as November 23, 2021, after the inspection, Form 483, and subsequent correspondence with the FDA, and less than a month before the FDA's issuance of the Warning Letter, Salmon assured investors that he had "very good interactive conversations with FDA."

3. The Month-Long Inspection, Form 483, and Post-Inspection Communications with the FDA Reveal Defendants' Knowledge of the Severity in the FDA's Findings

164. According to the FDA's Investigations Operations Manual (the "Manual"), which is "the primary operational reference for FDA employees who perform field investigational activities," a Form 483 "is intended for use in notifying the inspected establishment's top management in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts . . . which were observed during the inspection." The Manual provided "general principles" to which Form 483s "should adhere":

> 1. Observations which are listed ***should be significant*** and correlate to regulated products or processes being inspected.
>
> 2. ***Observations of questionable significance should not be listed on the FDA-483 . . . but will be discussed with the firm's management*** so that they understand how uncorrected problems could become a violation.

165. The Manual reiterated that for Form 483s "to be [a] useful and credible document[]," each observation included in the form "should be significant" and "[t]he observations should be ranked in order of significance." The Manual also indicated the steps

investigators should take to make management aware of the issues uncovered during the inspections:

> Investigators and analysts should make every reasonable effort to discuss all observations with the management of the establishment as they are observed, or on a daily basis, to minimize surprises, errors, and misunderstandings when the FDA 483 . . . is issued. This discussion should include those observations, which may be written on the FDA 483 . . . and those that will only be discussed with management during the closeout meeting.

166. As described above, the July 7, 2021 Form 483 was presented to management and cited three categories of severe and pervasive deficiencies, as follows: (1) "Procedures for corrective and preventive action have not been adequately established"; (2) "Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary"; and (3) "Written MDR procedures have not been implemented." Particular facts the FDA cited in the Form 483 include:

- Medtronic's Field Product Impact Assessments, meant to calculate the risk associated with the failed retainer rings in the MiniMed 600 Series infusion pumps, repeatedly "used the same ***underestimated calculation for probability of occurrence*** and concluded again that the risk remained in Zone [REDACTED] ***even after a significant increase in complaints***."

- In Medtronic's June 2021 Field Product Impact Assessment, the "probability of occurrence" was "underreported" because Medtronic considered the "Total Shipment of Affected Product" rather than "the number of products actually in the field," and thus included in its calculation "devices that are not in use by patients, thereby under-estimating the probability of occurrence."

- Before Medtronic issued its safety notification regarding the clear retainer ring in November 2019, Medtronic had "received more than [REDACTED] complaints for this retainer ring issue; [REDACTED] complaints were reported to the FDA as Medical Device Reports (MDRs), ***including three deaths*** . . . , [REDACTED] ***serious injuries***

. . . and [REDACTED] malfunctions that could result in death or serious injury if the malfunction was to recur. . . ."

- While Medtronic "sent notifications to all customers with the affected pumps," "Technical Support personnel were instructed to tell customers that this field action was ***not a recall***."

- Medtronic "continue[d] to receive reports of failures with the re-designed black retainer rings." "As of 05/25/2021, your firm [Medtronic] has received [REDACTED] complaints for defective black retainer rings, including [REDACTED] ***complaints reported as serious injury MDRs*** . . . , and [REDACTED] complaints reported as malfunction MDRs . . . . Analysis of the [REDACTED] returned defective devices with black retainer rings show that ***your firm confirmed the failures, but no formal investigation was initiated***."

- Medtronic "***failed to submit Medical Device Reports*** (MDRs) for [REDACTED] customer complaints (dated 09/23/2016 – 05/12/2021) related to MiniMed 600 Series Insulin pump retainer ring failures where ***the returned product analysis confirmed that the reservoir was unable to lock into place***. . . . all of these complaints were received after the Field Product Impact Assessment (Version A, dated 06/23/2016) concluded that the failure of the ring could potentially result in under delivery of insulin leading to hyperglycemia, severe hyperglycemia, or diabetic ketoacidosis; or over delivery of insulin leading to mild or severe hypoglycemia or death."

- Medtronic "failed to submit [REDACTED] MDRs within [REDACTED] of becoming aware of information that reasonably suggests that MiniMed Infusion pumps may have caused or contributed to a death or serious injury. These MDRs (submitted between February 2020 and June 2021), include [REDACTED] MDRs ***submitted more than 100 days from the aware date***. . . ."

167. On July 7, 2021, the same day that the FDA transmitted the Form 483 to Medtronic, Medtronic and the FDA held a "closeout" or a "closing meeting" led by Ms. Pulver, the FDA investigator.

168. As described above, Salmon sent no fewer than five letters to the FDA regarding the Diabetes Group's attempts to rectify the pervasive deficiencies. These letters –

sent contemporaneously with Defendants' misleading statements – further establish Salmon's intimate knowledge of the problems imperiling the MiniMed Facility and the 780G approval process.

169. Salmon's personal and consistent involvement in communications with the FDA during and after the inspection supports an inference of his personal knowledge ***and*** the knowledge of the other members of Medtronic's Executive Committee, which included Martha and Parkhill. In fact, Martha explained during the October 14, 2020 Investor & Analyst Meeting that the Executive Committee all "sit around in a monthly meeting" to discuss, among other things, strategic issues affecting the Company. And in its December 14, 2020 press release announcing Salmon's promotion to EVP and President Cardiovascular Portfolio, Medtronic noted that Salmon worked "closely with the other portfolio leaders and members of the Executive Committee on enterprise-level strategy and value creation."

4. The Rarity and Critical Nature of Inspections and Forms 483 Support an Inference of Scienter

170. For Medtronic, inspections and deficiencies on Form 483 arising from inspections are exceedingly rare. During the Class Period, the FDA did not conduct any other inspections at the MiniMed Facility.[20] Prior to the June-July 2021 inspection, the MiniMed Facility had not been inspected since February 2019, and that inspection did not result in any findings on a Form 483.[21]

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[20] https://datadashboard.fda.gov/ora/firmprofile.htm?FEIs=3003166194&/identity/3003166194.

[21] *Id.* The inspection, completed February 15, 2019, was classified as "no action indicated" ("NAI"). An NAI classification indicates "no objectionable conditions or practices were found during the inspection (or the objectionable conditions found do not justify further

171. Company-wide, inspection findings were even rarer. In FY 2021, ***99%*** of the Company's 242 external regulatory inspections resulted in no findings.[22] In other words, only 3 of the 242 regulatory inspections conducted at Medtronic facilities resulted in findings. In FY22, ***95%*** of the Company's external regulatory inspections resulted in no findings.[23] For FDA inspections specifically, Medtronic received ***0.02 findings*** per inspection during FY21, equivalent to just a single finding across every 50 FDA inspections.[24]

172. FDA inspection findings were also a key component of Martha's and Parkhill's executive compensation during the Class Period. For example, in its FY21 Proxy Statement, Medtronic described that executives' compensation could be modified, or adjusted downward, based on the number of FDA inspection findings in a given year:

> **Focus on Quality**. The Company emphasizes quality: payouts under its annual incentive plan can be reduced if a quality compliance modifier performance threshold is not achieved. The quality modifier, which may reduce but not increase a payout, is designed to align Medtronic employees with the Medtronic Mission, "To strive without reserve for the greatest possible reliability and quality in our products." ***The modifier uses Food and Drug Administration inspection observations to provide a standardized and rigorous assessment of the company's product and process quality***.[25]

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regulatory action)." *See* https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspections-database-frequently-asked-questions.

[22] FY21 Integrated Performance Report.

[23] FY22 Integrated Performance Report.

[24] FY21 Integrated Performance Report.

[25] Medtronic FY21 proxy statement on Schedule 14A; filed with the SEC on August 27, 2021.

The Proxy Statement described that for FY21 (*i.e.*, before the July 7, 2021 inspection and Form 483), the quality modifier (*i.e.*, the number of FDA inspection findings) resulted in no negative adjustments to the executive compensation payouts.

173. Because FDA inspections and deficiency findings on Forms 483 were rare and notable events, the inference is strong that Martha, Parkhill, and Salmon were aware of the June-July 2021 inspection and the July 7, 2021 Form 483 when they occurred. The fact that Martha's and Parkhill's compensation was directly tied to inspection findings further supports an inference of their scienter.

5. Martha (as CEO) and Parkhill (as CFO) Were Routinely Apprised of the Product Quality Failures and FDA Inspections

174. As Medtronic stated in its 2021 Integrated Performance Report released on October 12, 2021, "[f]ormal oversight of quality ultimately sits with our board and executive leadership." As a member of the Board of Directors, Martha was routinely apprised of quality and FDA regulatory issues, including the MiniMed 600 issues and the FDA inspections arising from the recall, by the Quality Committee, whose mission is to assist the Board in its oversight of the quality and safety of Medtronic's products. The Quality Committee presented to the Board regarding, among other things, "***the Company's response to quality and quality system assessments conducted by the Company and by external regulators*** (including without limitation FDA and various notified bodies)" and "***the Company's response to material quality and field actions***." The Quality Committee "may request any director, officer or employee of the Company or the Company's outside counsel to attend a meeting of the Committee or to meet with any members of, or consultants to, the

Committee." Moreover, the Quality Committee "report[ed] on its activities to the Board ***regularly***." By virtue of his membership on the Board, Martha was indisputably aware of the severe and pervasive quality issues identified in the Form 483.

175. In addition to the information reported to him through the Quality Committee, Martha also received regular reports from Medtronic's chief quality officer ("CQO"). The Company's CQO sat on "the executive committee ***and report[ed] directly to the CEO on all quality matters***." Accordingly, Martha, as CEO and a member of the Board, was regularly apprised of the quality and regulatory issues alleged herein.

176. The Medtronic Code of Ethics for Senior Financial Officers, which implicates Martha (as CEO) and Parkhill (as CFO), further supports scienter. The Code of Ethics for Senior Financial Officers provides that "[t]he CEO and all Senior Financial Officers[26] are responsible for full, fair, accurate, timely, and understandable disclosure in the reports and documents that the Company files with, or submits to, the SEC and in other public communications made by the Company." It also requires that the CEO and/or each Senior Financial Officer "promptly bring to the attention of the General Counsel or the CEO any material information of which he or she may become aware that affects the disclosures made by the Company in its public filings." The Code of Ethics for Senior Financial Officers further provides that "[t]he CEO and each Senior Financial Officer shall promptly bring to the attention of the General Counsel or the CEO any information he or she may have

[26] The Code of Ethics for Senior Financial Officers defines "Senior Financial Officers" to include "the CEO and the CFO, Treasurer and Corporate Controller and other senior financial officers performing similar functions who have been identified by the CEO."

concerning evidence of a material violation of the securities or other laws, rules or regulations applicable to the Company and the operation of its business, by the Company or any agent thereof, or any violation of this Code of Ethics."

6. The Impact on Medtronic's Overall Business Supports Scienter

177. As discussed above, Medtronic announced the FDA's issuance of the Warning Letter on December 15, 2021. At that time, Defendants also announced that while the Company did "not expect an impact to the total company organic revenue growth and adjusted earnings per share guidance for the third quarter or full fiscal year 2022 that it issued on November 23, 2021," it did expect an impact on the Diabetes Group's organic revenue and further modeled that for FY23, the impact on the Company's 2023 revenue growth was 0.5% to 1%.

178. Then, on May 26, 2022, Medtronic told investors during its Q4 2022 earnings call that the Company no longer expected to receive timely FDA approval for the MiniMed 780G, and therefore had "elected not to include it in our guidance" for its FY23 revenue. The Company further announced that it expected the Diabetes Group's organic revenue growth to decline 6% to 7%. To put the impact of this revenue miss in context, ***one percentage point of FY23 revenue growth is equal to approximately $325 million in revenue***. Medtronic's extreme step of not including the MiniMed 780G pump in its guidance contributes to the inference that the quality problems identified in the Warning Letter were material, and were therefore known by Defendants during the Class Period.

179. In addition, U.S. patients who had been waiting for the MiniMed 780G's approval now turned to competitor products. As Salmon explained on Medtronic's May 26, 2022 Q4 2022 earnings call: "So within the U.S., the dynamic is obviously people waiting for the new technology to come before prescribing it for new patients or some patients not wanting to wait for it and moving on to competitive therapies." Following the Class Period on Medtronic's November 22, 2022 Q2 2023 earnings call, the new President of the Diabetes Group, Que Dellara, admitted that the U.S. market was facing "attrition." Martha, meanwhile, acknowledged at the Evercore ISI HealthCONx Conference on November 29, 2022 that the Warning Letter had created a "log jam" for a "a lot of technology" "that we're getting further along outside the U.S. in terms of regulatory approvals." The long-term financial and competitive effects of failing to obtain approval for the MiniMed 780G pump contributes to an inference that Defendants knowingly concealed the adverse facts surrounding the 780G.

7. Defendants' SOX Certifications Support an Inference that Material Information Relating to Product Defects, the Inspection, and the Form 483 Was Made Known to the Certifying Defendants

180. Defendants' scienter is also underscored by the SOX certifications signed by Martha and Parkhill. These certifications acknowledged their responsibility to investors for establishing and maintaining controls to ensure that material information about Medtronic was made known to them and that the Company's disclosure controls and financial reporting controls were operating effectively.

181. During the Class Period, Martha and Parkhill certified that they had undertaken an assessment and evaluation of the Company's disclosure controls to ensure that Medtronic's SEC filings did not contain any false information, including controls designed to ensure all relevant and material information was reviewed by Martha and Parkhill prior to certifying those filings pursuant to SOX. This further establishes that these Defendants knowingly misled the market, or were reckless in making such representations and executing such certifications, because Martha and Parkhill were, at that time, aware of and/or recklessly disregarded material weaknesses in Medtronic's system of internal controls concerning financial reporting and disclosures regarding the same that were not disclosed to the investing public.

8. Salmon's Stock Sales Support a Motive to Commit Fraud

182. Salmon was motivated to issue the alleged misrepresentations to capitalize on an artificially increased stock price by selling a total of 28,419 shares of his personally held Medtronic stock during the Class Period, for gross proceeds of more than ***$3.8 million***. Salmon's sales were unusual in timing and amount, executed to maximize personal benefit from the fraud. Indeed, Salmon dumped almost half of his Medtronic holdings for proceeds of $3.8 million in a ***single day*** on August 25, 2021 in two suspiciously timed sales, when Medtronic's stock price was trading near its Class Period high. Notably, this sale came the ***day after*** he misleadingly told the market on August 24, 2021 that he was seeing "really good interactive back and forth" with the FDA and that the approval process for 780G was "on track" and "making good progress." Critically, Salmon's August 25, 2021 sales were open market trades – in other words, they were executed ***outside of a Rule 10b5-1 trading***

plan. Moreover, in contrast to Salmon's suspiciously timed and sized August 25, 2021 sales, Salmon had sold ***zero*** Medtronic shares in the three years prior to the Class Period.

IX. LOSS CAUSATION

183. Defendants' wrongful conduct, as alleged herein, directly and proximately caused Plaintiff's and Class members' economic loss. Plaintiff's claims for securities fraud are asserted under the fraud-on-the-market theory of reliance. The markets for Medtronic's common stock were open, well-developed, and efficient at all relevant times. During the Class Period, as detailed herein, Defendants engaged in a scheme and made misleading statements and omissions regarding product quality issues with the MiniMed 600 Series pumps, the approval process for the MiniMed 780G pump, Medtronic's facility quality, and Medtronic's regulatory compliance. Defendants' conduct artificially inflated the price of Medtronic common stock and operated as a fraud or deceit on the Class.

184. The Class Period inflation in Medtronic's stock price was removed when information concealed by Defendants' scheme and misleading statements and omissions was revealed to the market. The information was disseminated through partial disclosures that revealed the nature and effect of Defendants' alleged conduct. These disclosures, as more particularly described below, removed artificial inflation from Medtronic common stock, causing economic injury to Plaintiff and other members of the Class.

185. The corrective impact of the partial disclosures during the Class Period alleged herein, however, was tempered by Defendants' continued scheme and misleading statements that continued to conceal the true nature and extent of Defendants' fraud. Each partial disclosure did not on its own fully remove the inflation from Medtronic's stock price,

because it only partially revealed the nature and extent of the fallout from Defendants' previously misrepresented and concealed conduct. Defendants' continued scheme, misrepresentations, and omissions maintained the price of Medtronic common stock at a level that was inflated by fraud, inducing members of the Class to continue purchasing shares in Medtronic even after Defendants' partial disclosures.

186. The disclosures that corrected the market price to eliminate the inflation maintained by Defendants' fraud are detailed below. These stock price declines were due to firm-specific, fraud-related disclosures and not the result of market, industry, or firm-specific, non-fraud factors. The following stock price declines and descriptions thereof are not necessarily comprehensive since fact and expert discovery are not complete.

187. A partial disclosure entered the market on February 12, 2020, when the FDA announced a Class I recall – the most serious type of recall – of the MiniMed 600 Series insulin pumps, which expanded the scope of the issues with these products beyond Medtronic's earlier Field Safety Notification in November 2019. As a result of this partial disclosure, the price of Medtronic stock declined more than 2% on volume of more than 7.6 million shares to close at $116.49 per share on February 12, 2020. In contrast to the decline in Medtronic common stock, the S&P 500 Index and the S&P 500 Health Care Equipment Index both increased slightly during this period.[27] Analysts commented on the disappointing news and attributed Medtronic's stock price decline to the announcement of the Class I

[27] For purposes of comparing its stock price performance vis-à-vis its peers and relevant market, Medtronic referred investors to the S&P 500 Index and the S&P 500 Health Care Equipment Index.

recall. For example, an analyst at Evercore ISI stated, "MDT shares are off on a Street Account article highlighting the recall of its 670G insulin pumps . . . ." Although the stock price reacted negatively to the February 12, 2020 announcement of the Class I recall, the reaction was tempered because, according to Evercore ISI, Medtronic indicated it "believes the occurrence of 'retainer ring breaking' is less than 0.1%" and it "told its customer that it will replace a small number of pumps that have the damaged rings – cost impact expected to be minimal." Defendants' continued concealment, misrepresentations, and omissions of the truth maintained artificial inflation in the price of Medtronic common stock.

188. On December 15, 2021, Medtronic revealed that it had received the Warning Letter from the FDA regarding the MiniMed Facility. Specifically, Defendants stated that the Warning Letter "was issued following an inspection that concluded in July 2021 related to recalls of the MiniMed™ 600 Series insulin infusion pump" and other products, and that "[t]he warning letter focuses on the inadequacy of specific medical device quality system requirements at the Northridge facility in the areas of risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events." That same day, Medtronic announced that as a result of the Warning Letter, including new "uncertainty on the timing of U.S. Diabetes product approvals," the Company was "adjusting its expectations for its Diabetes business organic revenue." Specifically, Medtronic lowered its Diabetes Group guidance, announcing "declines in the high-single digit range for the third fiscal quarter and the mid-single digits range for the full fiscal year 2022, down modestly from previous guidance of mid- and low-single digit declines, respectively." On December 16, 2021, Defendants held an analyst meeting where they further discussed the fallout from

the Warning Letter. On December 17, 2021, J.P. Morgan downgraded Medtronic shares, citing "setbacks to the company's marquee pipeline assets," including the MiniMed 780G. As a result of these disclosures, the price of Medtronic stock declined more than 9.9% on volume of more than 59.5 million shares to close at $100.63 per share on December 17, 2021. In contrast to the sharp decline in Medtronic common stock during this period, the S&P 500 Index was flat and the S&P 500 Health Care Equipment Index was up by approximately half-a-percent during this period.

189. On May 26, 2022, Medtronic issued a press release on Form 8-K announcing its financial results for the fourth quarter and full year of FY22. Defendants announced that Diabetes Group revenue decreased 3% for FY22. Further, Defendants disclosed that Medtronic expected even worse performance for the Diabetes Group in FY23, projecting that Diabetes Group revenue would decline 6% to 7% year-over-year. On the earnings call the same day, Defendants admitted that the Company's 2023 projections assumed that the MiniMed 780G would not receive FDA approval in FY23. On the same call, Salmon acknowledged the Company still needed "to improve and sustainably improve the quality system," as outlined in the Form 483 and Warning Letter. As a result of these disclosures, the price of Medtronic stock declined 5.8% on volume of approximately 12.7 million shares to close at $99.44 per share on May 26, 2022. In contrast to the decline in Medtronic's stock price, the S&P 500 Index was up nearly 2% and the S&P 500 Health Care Equipment Index was flat during this period.

X. POST-CLASS PERIOD DEVELOPMENTS

190. In order to lift the Warning Letter, the MiniMed Facility was required to pass a re-inspection by the FDA. That inspection closed on March 1, 2023. On April 25, 2023, Medtronic announced that the FDA "lifted the warning letter received at the company's Diabetes headquarters in Northridge, California, in December 2021." This announcement came contemporaneously with Medtronic's announcement after hours on April 21, 2023 that the Company had received FDA approval of the 780G.

191. Notably, this timeline is consistent with CW-2's account. In particular, CW-2 stated it would take approximately one to two years to remediate the deficiencies identified in the July 7, 2021 Form 483. As it turned out, the FDA did not lift the Warning Letter until 21 months after issuance of the Form 483. Consistent with CW-2's statement that "it was physically impossible to get approval for any product while under a warning letter," Medtronic announced the lifting of the Warning Letter and FDA approval of the 780G ***two business days apart***.

192. Industry experts and market analysts alike recognized that the delay in the FDA's approval of the 780G was the direct result of the quality control issues at the MiniMed Facility giving rise to the Form 483 and Warning Letter:

Morningstar, April 25, 2023:

> The FDA has taken more than twice as long than usual to approve the 780g. Though Medtronic had received European regulatory approval of the 780g nearly three years ago, and ***it had submitted its application with the FDA two years ago, a defective retainer ring used in the earlier 630g and 670g pumps that locks the insulin cartridge into place, if damaged, could lead to incorrect dosing of insulin. This spurred a large-scale product recall and prompted the FDA to withhold approval of the 780g***. These developments led to U.S. diabetes revenue falling 17% in fiscal 2022,

followed by another 15% decline year to date in fiscal 2023. While the 780g appears off to a strong start outside the U.S., that strength wasn't enough to wholly offset the weakness in the U.S.

Medical Device and Diagnostic Industry, April 24, 2023:

> Medtronic originally submitted for FDA approval of the MiniMed 780G in 2021, and received a regulatory license from Health Canada in 2022. ***But FDA approval was delayed by quality control problems at the company's manufacturing facility, which triggered a warning letter for Medtronic's diabetes unit***. That warning letter stemmed from an inspection that concluded in July 2021 related to recalls of the MiniMed 600 series insulin infusion pump, and a remote controller device for MiniMed 508 and Paradigm pumps.

diaTribe Learn, April, 21, 2023:

> The Medtronic MiniMed 780G was approved by the FDA in April 2023 for those with type 1 diabetes over age 7, paving the way for Medtronic to distribute its latest insulin pump across the country, and Medtronic recently announced shipments of the system were underway in the U.S. ***The MiniMed 780G was submitted for FDA approval in 2021 but faced a delay due to quality control issues at Medtronic's manufacturing facility***. The device was approved in Europe in 2020 and Canada in November 2022.

Fierce Biotech, April 24, 2023:

> ***Medtronic originally submitted the MiniMed 780G system for FDA approval in spring 2021, but the regulatory decision was delayed after the company spent much of last year correcting quality control issues that the agency had discovered at the headquarters of Medtronic's diabetes business and outlined in a late 2021 warning letter***.
>
> In the meantime, the 780G technology scored regulatory clearances in dozens of other countries, and its maker continued to release study data proving the system's mettle.

Analysts also recognized that Medtronic's Friday, after-hours announcement that the FDA finally approved the 780G signaled that the MiniMed Facility had passed re-inspection and the Warning Letter was lifted:

TD Cowen, April 21, 2023:

> ***This afternoon, the FDA announced that it has approved MDT's MiniMed 780G system*** for modifications to the SmartGuard technology and for expanding the indications for use to include the Guardian 4 sensor. . . . ***We assume the Northridge facility has passed re-inspection***, although the agency's inspection database has not been updated with that information as of 4:45pm ET on Friday.

XI. APPLICABILITY OF THE PRESUMPTION OF RELIANCE AND THE FRAUD-ON-THE-MARKET DOCTRINE

193. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- defendants engaged in a scheme and made public misrepresentations or failed to disclose material facts during the Class Period;
- the scheme, misrepresentations, and omissions were material;
- Medtronic common stock are traded in an efficient market;
- the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- the Company's common stock was traded on the NYSE and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased, acquired, and/or sold Medtronic common stock between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

194. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

195. Plaintiff and the members of the Class are also entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v.*

United States, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

XII. THE PSLRA SAFE HARBOR DOES NOT APPLY

196. The Defendants are liable for any misleading forward-looking statement ("FLS") pleaded that were contained in Medtronic's registration statement because the PSLRA's Safe Harbor provisions do not apply to "a forward-looking statement . . . that is . . . contained in a registration statement of, or otherwise issued by, an investment company." 15 U.S.C. §78u-5(b)(2)(B).

197. In addition, Defendants' verbal "Safe Harbor" warnings accompanying its oral FLS issued during the Class Period were ineffective to shield those statements from liability.

198. The Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer at Medtronic who knew that the FLS was false.

XIII. CLASS ACTION ALLEGATIONS

199. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Medtronic common stock during the Class Period (the "Class") and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein and the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

200. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Medtronic common stock was actively traded on the NYSE. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Medtronic or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

201. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

202. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

203. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether the Scheme Defendants engaged in a scheme or course of business that operated as a fraud or deceit on investors;
- whether statements made by Defendants to the investing public during the Class Period misrepresented or omitted material facts about the business, operations, and management of Medtronic;

- whether Defendants caused Medtronic to issue false and misleading financial statements during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Medtronic common stock during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

204. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XIV. CLAIMS

COUNT I
Violations of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

205. Plaintiff repeats and realleges each and every allegation in ¶¶1-204 above as if fully set forth herein.

206. This Count is based upon §10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder by the SEC. Defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that: (a) the Scheme Defendants employed devices, schemes, and artifices to defraud; (b) the Defendants made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in

light of the circumstances under which they were made, not misleading; or (c) the Scheme Defendants engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and the Class in connection with their purchase of Medtronic common stock during the Class Period.

207. From May 23, 2019 through December 15, 2021, the Scheme Defendants, during the time they held their positions at Medtronic, engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; and employed devices, schemes, and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, from May 23, 2019 through December 15, 2021, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Medtronic securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Medtronic securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, the Scheme Defendants, and each of them, took the actions set forth herein.

208. In addition, from August 24, 2021 through December 2, 2021, the Defendants made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading. The Defendants' untrue statements of material fact were intended to, and, from August 24, 2021 through December 2, 2021, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and

maintain the market price of Medtronic securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Medtronic securities at artificially inflated prices. In furtherance of this wrongful course of conduct, the Defendants, and each of them, took the actions set forth herein.

209. Pursuant to the above wrongful course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases, and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Medtronic securities. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Medtronic's finances and business prospects.

210. By virtue of their positions at Medtronic, the Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, the Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to the Defendants. Said acts and omissions were committed willfully or with reckless disregard for the truth. In addition, each of the Defendants knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

211. Information showing that the Defendants acted knowingly or with reckless disregard for the truth is peculiarly within the Defendants' knowledge and control. As the

senior managers and/or directors of Medtronic, Defendants had knowledge of the details of Medtronic's internal affairs.

212. Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, Defendants were able to and did, directly or indirectly, control the content of the statements of Medtronic. As officers and/or directors of a publicly held company, Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Medtronic's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of Medtronic securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Medtronic's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Medtronic securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities, and/or upon statements disseminated by Defendants, and were damaged thereby.

213. During the Class Period, Medtronic securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Medtronic securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise

acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Medtronic securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Medtronic securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

214. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

215. As a direct and proximate result of the Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II
Violations of §20(a) of the Exchange Act (Against All Defendants)

216. Plaintiff repeats and realleges each and every allegation in ¶¶1-215 above as if fully set forth herein.

217. During the Class Period, Defendants, during the time they held their positions at Medtronic, participated in the operation and management of Medtronic, and conducted and participated, directly and indirectly, in the conduct of Medtronic's business affairs. Because of their senior positions, they knew the adverse non-public information about Medtronic's business as alleged herein.

218. As officers and/or directors of a publicly owned company, Defendants had a duty to disseminate accurate and truthful information with respect to Medtronic's financial condition and results of operations, and to correct promptly any public statements issued by Medtronic which had become materially false or misleading.

219. Medtronic had the power to control and influence the other Defendants, and other Company executives through its power to hire, fire, supervise and otherwise control the actions of its employees and their salaries, bonuses, incentive compensation and other employment considerations. By virtue of the foregoing, Medtronic had the power to influence and control, and did influence and control, directly or indirectly, the decision making of Defendants, including the content of their public statements.

220. Because of their positions of control and authority as senior officers, Defendants were able to, and did, control the contents of the various reports, press releases, and public filings which Medtronic disseminated in the marketplace during the Class Period concerning Medtronic's business and results of operations. Throughout the Class Period, Defendants exercised their power and authority to cause Medtronic to engage in the wrongful acts complained of herein. Defendants, therefore, were "controlling persons" of Medtronic within the meaning of §20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Medtronic securities.

221. Each of the Defendants, therefore, acted as a controlling person of Medtronic. By reason of their senior management positions and/or being directors of Medtronic, each of the Defendants had the power to direct the actions of, and exercised the same to cause, Medtronic to engage in the unlawful acts and conduct complained of herein. Each of the

Defendants exercised control over the general operations of Medtronic and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

222. By reason of the above conduct, Defendants are liable pursuant to §20(a) of the Exchange Act for the violations committed by Medtronic.

XV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that this action is a proper class action, and certify Plaintiff as a Class Representative under Rule 23 of the Federal Rules of Civil Procedure and appointing Robbins Geller Rudman & Dowd LLP as Class Counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including reasonable attorneys' fees, accountants' fees, and experts' fees, and other costs and disbursements; and

D. Awarding such other and further relief as this Court may deem just and proper.

XVI. DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

DATED: October 21, 2024

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